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No. 96-188

IN THE

Supreme Court of the United States

October Term, 1996

GENERAL ELECTRIC COMPANY, WESTINGHOUSE ELECTRIC CORPORATION, AND MONSANTO COMPANY,
Petitioners,

v.

ROBERT K. JOINER AND KAREN P. JOINER,
Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR RESPONDENTS

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QUESTION PRESENTED

What is the standard of appellate review for trial court decisions excluding expert testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)?

TABLE OF CONTENTS

TABLE OF AUTHORITIES

BRIEF FOR RESPONDENTS

STATEMENT

Respondent Robert K. Joiner was diagnosed with lung cancer in 1991 at age 37. He and his wife (respondent Karen P. Joiner) filed suit, alleging that products manufactured and sold by petitioners, to which Joiner had been exposed occupationally, had contributed to his unusually early onset of lung cancer.[1]

A. Factual Background

Petitioner Monsanto Company was the sole manufacturer of polychlorinated biphenyls ("PCBs") in the United States from 1935 until 1977, when PCBs were banned by federal law. App. 36a. PCBs are man-made chemicals that were purchased during this period by petitioners General Electric Company ("GE") and Westinghouse Electric Corporation for use as a component of fire-resistant dielectric fluid in electrical transformers that they marketed to utilities. PCBs have long been regarded as extremely hazardous to humans and, in particular, as being "highly toxic carcinogen[s]." *Midlantic Nat'l Bank v. New Jersey Dep't of Envtl. Protection*, 474 U.S. 494, 497 (1986).[2] They are classified as

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[1] References to the appendix attached to the petition for certiorari are styled "App. __a," and to the Joint Appendix, "J.A. __." References to the supplemental appendix that appears at the end of this brief, containing record excerpts pertinent to arguments advanced by petitioners in their merits brief that were not raised in the petition, see note 52, *infra*, are styled "S.A. __." References to "Joiner" denote respondent Robert K. Joiner, not respondent Karen P. Joiner, unless otherwise indicated.

[2] *See* Toxic Substances Control Act, 15 U.S.C. § 2605(a) & (e) (1976) (banning the production and sale of PCBs, with narrow exceptions, effective January 1, 1978, based on congressional finding that "there is a reasonable basis to conclude that [PCBs] present[] or will present an unreasonable risk of injury to health or the environment"); *Yaffe Iron & Metal Co., Inc. v. EPA*, 774 F.2d 1008, 1010 n.1 (10th Cir. 1985) ("PCBs are extremely toxic to humans and wildlife, and pose carcinogenic and other risks to humans"); *Environmental Defense Fund, Inc. v. EPA*, 636 F.2d 1267, 1270 (D.C. Cir. 1980) ("Epidemiological data and experiments on laboratory animals indicate that

probable human carcinogens by federal and international health authorities.[3]

Routinely present in transformers containing PCBs were two chemical derivatives of PCBs produced in the process of manufacturing them and through heat and other conditions present during their use: polychlorinated dibenzofurans ("furans") and, to a lesser extent, polychlorinated dibenzodioxins ("dioxins"). The parties' experts agreed on this point, although they disagreed about the amounts of these contaminants typically present in the transformers along with PCBs.[4] Furans and dioxins are even more

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exposure to PCBs pose[s] carcinogenic and other risks to humans."); *Environmental Defense Fund v. EPA*, 598 F.2d 62, 76 & n.54 (D.C. Cir. 1978) (summarizing legislative history of ban on PCBs).

[3] *See, e.g.*, 62 FED. REG. 24887, 24891 (May 7, 1997) ("PCBs are classified as [Class I], group B2, probable human carcinogens by EPA and are listed as substances which may reasonably be anticipated to be human carcinogens in the NIEHS/NTP Annual Report on Carcinogens.") (citations omitted); 54 FED. REG. 22062, 22089 (May 22, 1989) ("There are several animal studies which show PCB mixtures to be carcinogenic. As discussed in the November 1985 proposal, EPA believes these studies are sufficient to classify PCBs in Group B2, probable human carcinogen. . . . Three recently published epidemiologic studies of PCB-exposed populations reported statistically significant excesses of tumors of the lung, liver, gastrointestinal tract and hematopoietic system."). In 1987, the International Agency for Research on Cancer (IARC) of the World Health Organization, after considering "the combined evidence from human and experimental animal studies . . . concluded that PCBs are probably carcinogenic for humans." WORLD HEALTH ORGANIZATION, POLYCHLORINATED BIPHENYLS AND TERPHENYLS 478 (2d ed. 1993) ("hereinafter "WHO"); *see also* S.A. 10, 16, 22 (Teitelbaum); S.A. 62 (Cole). One of petitioners' experts acknowledged, with remarkable understatement, that "there are credible scientists who hold the view that PCBs are an established human carcinogen." J.A. 235 (Cole).

[4] Joiner's experts, in a portion of their testimony that petitioners never sought to exclude as inadmissible, testified to the routine presence of these contaminants in PCB transformer fluids. *See* J.A. 405 (Schecter) (furans "are usually found in PCB transformer fluids, as reported in numerous reports and at many scientific meetings"); S.A. 49 (Schecter) (additional furans, and some dioxin, are created from heating of the PCBs during their use); J.A. 456 (Teitelbaum) (furans "are generally believed to contaminate all transformers at varying concentrations when PCBs, oxygen, and electric current combine," as a result of lightning strikes, overheating, fires and arcing of transformers). GE's

carcinogenic than PCBs.[5]

Joiner's complaint alleged that during the period in which GE and Westinghouse were manufacturing transformers containing PCB dielectric fluid, they and Monsanto were all aware of the dangers.[6] "Health problems associated with the manufacture of PCBs" were reported in the literature as early as 1936, with the first fatalities in workers reported in 1937, in a study warning that typical levels of occupational exposure to PCBs were unsafe.[7]

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top scientist on PCBs agreed that furans and dioxins "were not intentional constituents, but they have always been there" in its PCB-based dielectric fluids, although he opined that the amounts were "toxicologically insignificant." S.A. 73 (Brown). *See also* S.A. 64-65 (Hamilton). One of the leading scientific references on the subject, cited by petitioners, states that furans "are contaminants in commercial PCB mixtures . . . at levels ranging from a few mg/kg up to 40 mg/kg," and that these furans "contribute significantly to" the toxicity of the PCB mixtures. WHO, *supra* note 3, at 21-22 (cited in Pet. Br. 3 n.2).

[5] *See, e.g.*, 62 FED. REG. 24887, 24891 (May 7, 1997) (noting evidence that dioxins are "a potent carcinogen," indeed, based on one EPA analysis, "the most potent chemical carcinogen that EPA has regulated); CHEMICAL WEEK, Apr. 16, 1997, at 8 ("[D]ioxin's toxicological and regulatory profile is growing. . . . Cancer risk remains significant: In February the International Agency for Research on Cancer upgraded the most potent form of dioxin from a 'probable' to a 'known' human carcinogen."); Dieter Flesch-Janys, et al., *Exposure to Polychlorinated Dioxins and Furans (PCDD/F) and Mortality in a Cohort of Workers from a Herbicide-Producing Plan in Hamburg, Federal Republic of Germany*, 142 AM. J. OF EPIDEMIOLOGY 1165, (1995) (epidemiological study further confirming "the strong existing evidence of a carcinogenic effect of [furans and dioxins] in humans."). Petitioners' experts agreed on this point. *See, e.g.*, S.A. 65 (Hamilton) ("I believe that [furans] pose potential health risks to humans"); S.A. 73 (Brown) (dioxins are "a very potent agent" in promoting cancer).

[6] J.A. 68 (First Amended Complaint ¶ 6). Petitioners did not controvert these allegations in their motion for summary judgment.

[7] U.S. DEP'T OF HEALTH, EDUCATION & WELFARE, OCCUPATIONAL EXPOSURE TO POLYCHLORINATED BIPHENYLS (PCBS) 31-32 & nn. 120, 125 (1977) (hereinafter "HEW") (cited in Pet. Br. 3 n.2). *See also* WHO, *supra* note 3, at 19 (noting that commercial production of PCBs "began in 1930, and, during the 1930s, cases of poisoning were reported among men engaged in their manufacture . . . in some cases with fatal consequences.").

In 1975 Monsanto learned from a study of its workers involved in the manufacture of PCBs that "[t]he mortality due to lung cancer" ranged "from between three- and ten-fold, when compared to the figure expected, and the increased rate is significant." S.A. 80. *See also* S.A. 82 (followup analysis describing "highly significant" epidemiological evidence of a tripling of lung cancer risk). A separate 1976 Monsanto study provided further indications of a tripling of lung cancer risk associated with PCB exposure. S.A. 84. Monsanto continued producing PCBs for use in dielectric fluid until 1977, when it was forced to stop by federal law.

As for Westinghouse, as early as 1945 it warned its workers not to breathe vapors from its PCB fluids and to "avoid contact of it with the skin." S.A. 75. In 1947 it warned plant managers that the fluids were "highly toxic," posing a danger of "[c]hronic poisoning" that "could be fatal," and that "[c]are must be taken to prevent any appreciable contact of this material with the skin," and to use a combination of ventilation and/or respirators given the dangers posed by breathing in the vapors. S.A. 77-78. Although the current record on GE's knowledge of the hazards of PCBs, and the need for careful efforts to protect workers, is not nearly as extensive as on Westinghouse's knowledge, it does reflect that, by 1975, GE had at least one scientist in charge of studying safety concerns over PCBs, S.A. 73 (Brown), and that during this period GE had discussions with Westinghouse concerning the issue.[8]

PCB-based dielectric fluids were only used intentionally to build transformers that would operate in areas unusually subject to fire dangers, so that less than 0.2% of transformers in use by utilities nationwide were manufactured with the intent that they

[8] Deposition of Thomas O. Rouse at 73, 89. Early in the litigation the district court, with the parties' consent, stayed all discovery except with respect to the issue of causation. J.A. 59-66. It is clear, however, that by 1977 the need for careful precautions against occupational exposure to PCBs had become well established in the field. *See, e.g.*, HEW, *supra* note 7, at 145-46 (noting that "[t]he carcinogenic, teratogenic, dermatologic, and fetotoxic effects of PCBs" require the posting of warning signs, "[a]dequate ventilation," and the use of "PCB-resistant protective clothing and equipment, including respirators," among other precautions).

contain any PCBs or their typical furan and dioxin derivatives. App. 35a. Nearly all transformers manufactured by GE and Westinghouse were filled with dielectric fluid using mineral oil that should have been entirely free of such hazards. By the mid 1970s, however, both GE and Westinghouse had discovered that many millions of the mineral oil transformers that they had sold to utilities over the decades and that were still in service were contaminated with PCBs, as the result of negligent manufacturing techniques that had allowed improper mixing of the two types of dielectric fluids.[9]

Despite their knowledge that millions of their supposedly PCB-free mineral oil transformers were contaminated with PCBs, furans and dioxins, both GE and Westinghouse continued for years to provide warning labels and safety guidelines *only* with respect to the 0.2% of transformers that they specifically manufactured to contain PCBs.[10]

B. The Present Action

In 1973, when GE and Westinghouse were learning that many of the mineral oil transformers they had placed in service were contaminated with PCBs, furans and dioxins, respondent Robert K. Joiner began working as an electrician for the City of Thomasville, Georgia. Joiner's duties included working with and around electrical transformers manufactured by GE and Westinghouse, all

[9] J.A. 70-71 (First Amended Complaint ¶¶ 14, 18). *See also* 52 FED. REG. 10688, 10695 (Apr. 2, 1987) ("EPA estimates that there are . . . over 20 million mineral oil transformers contaminated with PCBs currently in use"); S.A. 6 (Teitelbaum). *See, e.g.*, Exhibit 12 to Opposition to Summary Judgment (letter to industry purchasing executives from Westinghouse marketing manager D.P. Keiser, dated Nov. 22, 1976); S.A. 69-70 (Rouse); S.A. 71 (Rouse) (stating that at GE plant, "[a] transformer could be inadvertently filled with [PCBs] and drained into a [mineral] oil line; equally so, a transformer could be inadvertently drained with [mineral] oil and drained into the [PCB] line. . . . [I]n all cases, these kinds of actions of mixing were unintentional. . . . I think you could characterize them as mistakes.").

[10] J.A. 71 (First Amended Complaint ¶¶ 17-19). *See, e.g.*, S.A. 53 (Joiner); Deposition of Thomas O. Rouse at 55-56.

of which used mineral oil dielectric fluid. App. 2a. Because Joiner's employer had received no indication that the supposedly PCB-free transformers contained any PCBs, furans or dioxins, Joiner took none of the precautions that had by then become well established as necessary for those working with these hazardous substances.[11] In repairing the transformers, Joiner routinely stuck his bare hands and arms into the toxic fluids and breathed in their heated fumes, and they often splashed over his body and sometimes into his eyes and mouth.[12]

By the late 1980s, as a result of testing done by Joiner's employer, it was discovered that approximately half of the supposedly PCB-free transformers were contaminated with PCBs, with approximately 20 percent of all transformers contaminated at levels considered extremely hazardous by the EPA. App. 2a, 36a.[13] Only then, after Joiner had been handling contaminated transformers for about fourteen years, did he finally receive the safety equipment and training necessary to handle them safely. J.A. 208-09 (Joiner); S.A. 51 (Joiner).

In 1991, Joiner was diagnosed with lung cancer, a remarkable occurrence given that he was only age 37, had a relatively brief smoking history, and had quit smoking a decade earlier. App. 3a & n.3. Expert testimony that petitioners never sought to exclude as inadmissible established that "lung cancer is extremely rare for a thirty seven year old white male in the United States" and in this case is the probable "result of exposure to other exogenous factors which lead to the rapid development of the malignancy," which are "often referred to as promoters and are what make, or promote, an essentially harmless initiated cell into a harmful malignant cancer." J.A. 444-45 (Frank). *See also* J.A. 453 (Teitelbaum) ("it is clearly

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[11] J.A. 71 (First Amended Complaint ¶ 19). *See, e.g.* J.A. 208, 211, 217-18 (Joiner); S.A. 51-53 (Joiner).

[12] App. 2a-3a & n.2, 37a. *See also* J.A. 207-08, 211-15, 218-19 (Joiner); S.A. 50-52 (Joiner); S.A. 8, 12 (Teitelbaum); S.A. 40, 48 (Schecter).

[13] According to one of petitioners' experts, the percentage of contaminated transformers was even higher earlier during Joiner's employment. S.A. 70 (Rouse).

extraordinary for lung cancer to develop in a 37 year old male with a brief smoking history which terminated eleven years prior to the onset of his cancer," strongly pointing "to the operation of other carcinogens and cocarcinogens in Mr. Joiner's cancer, since cigarette smoking is so unlikely to be a sufficient cause of lung cancer at his age"); J.A. 445 (Frank) ("It is more likely than not . . . that tobacco smoke served only as the initator of [Joiner's] cancer and that some other agent served as the promoter of the initated cells").[14]

Joiner and his wife filed suit against petitioners seeking damages on the basis that Joiner's exposure to PCBs and their derivatives, to which he had been exposed as a result of the contaminated transformers that he had worked with, had been a probable contributing factor to his early development of lung cancer.[15] The parties are in agreement that under Georgia law, Joiner may prevail even if his lung cancer would not have occurred but for his cigarette smoking, and even if he eventually would have contracted lung cancer, if he can prove that petitioners' products in some way aggravated his existing susceptibility to cancer, e.g., by accelerating its onset.[16]

C. Joiner's Expert Testimony on Causation

During discovery, Joiner produced two expert witnesses in support of his claim that transformers manufactured by GE and Westinghouse, containing PCBs, furans and dioxins manufactured by Monsanto, had contributed to his development of lung cancer.

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[14] One of petitioners' experts recently observed that even "a man who quits [cigarette smoking] at age 40" (more than a decade after Joiner quit) "will live on average 99% as long as a man who never smoked." Brad Rodu and Philip Cole, *The Rewards of Smoking Cessation*, 7 EPIDEMIOLOGY 111 (1996) (letter).

[15] J.A. 69-75 (First Amended Complaint ¶¶ 10-36).

[16] *See* Brief of Appellants, No. 94-9131, 11th Cir., at 7-10 (summarizing relevant law); Brief of Appellees at 34 (stating that "defendants [have never] contended that the plaintiffs must prove that PCBs were the 'sole' cause of Mr. Joiner's illness," and conceding that Joiner need only show that his cancer "was promoted by his exposure to PCBs"). *See, e.g., Holley v. Smallwood*, 330 S.E.2d 136, 136-37 (Ga. App. 1985).

Dr. Teitelbaum. Daniel T. Teitelbaum, M.D., a co-founder of both the American Academy of Clinical Toxicology and the American Board of Medical Toxicology, is a toxicology expert who teaches a variety of graduate-level courses in occupational and environmental toxicology and the epidemiology of toxic diseases. J.A. 447-48, 473. He has published more than forty articles on these subjects in peer-reviewed journals and has served as an editorial board member or reviewer for several peer-reviewed journals. J.A. 448, 477-83. Teitelbaum devotes 40 percent of his time to teaching and patient care and 60 percent of his time to consulting for the federal government, major corporations, and private individuals.[17] Teitelbaum frequently treats patients from the electrical trades and, as a result of this work, has "extensive knowledge of the handling of toxic substances, hazardous materials, electrical power, and other risks of a physical and chemical nature." J.A. 449.

Teitelbaum explained in detail the methodology he used to form an opinion on whether petitioners' products had probably contributed to the development of Joiner's lung cancer. He conducted "a comprehensive and traditional occupational medical assessment" of Joiner, utilizing "traditional medical assessment techniques," in which he spent several hours examining Joiner and

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[17] J.A. 169. In his consulting work, Teitelbaum has assisted a number of federal agencies in assessing the toxicity of chemicals and other substances — serving as chairman of an FDA panel, as a member of several EPA committees or panels, as a special consultant to OSHA on many occasions, and as a member of a blue-ribbon presidential panel that was formed to chart strategy for future EPA and NIH research concerning the health risks of emerging technologies. J.A. 447-48, 476-77. He has served as an advisor or panel member of several World Health Organization working groups and has taught federal judges on the subjects of toxicology and epidemiology, under the auspices of the Federal Judicial Center. J.A. 448. He has consulted on occupational and environmental toxicology issues for IBM, W.R. Grace, Amoco, Xerox, Motorola and Intel. J.A. 473. Despite petitioners' efforts to depict Teitelbaum as engaged in the full time delivery of expert testimony for tort plaintiffs, *see* Pet. Br. 7, he testifies, on average, at only three or four trials a year, and in some years he does not appear in court at all. J.A. 168.

taking his medical history;[18] reviewed Joiner's medical records; reviewed data on Joiner's workplace exposure to hazardous chemicals and other risk factors; and relied on his general knowledge of the field and his literature review of the health effects of PCBs and their derivatives, in combination with the above data, to reach a conclusion. J.A. 449-50; S.A. 3-12, 15-19; *see also* App. 9a (quoting summary of methodology).

When asked at his deposition whether his methodology constituted valid toxicology, Teitelbaum testified to the difference between the term "probable" as it is "used by epidemiologists" and "probable" as it is "used by clinicians," which "is what most of the world runs on. That is to say you look at all the information and you come to a conclusion that all the evidence together gives you the reasonable likelihood that your conclusion is clinically correct," producing "a valid conclusion based on the totality of the evidence presented," which "is an appropriate thing for a toxicologist to do." S.A. 18-19.

Based on this methodology, Teitelbaum concluded that it was probable that Joiner's "lung cancer was caused or contributed to in a significant degree by the materials with which he worked," including specifically PCBs and furans, S.A. 6, and that Joiner's "work with PCB contaminated mineral oil, mineral spirits, and mineral oil per se," along with "his family history" and "his smoking history," combined in a "multifactorial fashion . . . to result in lung cancer at a very young age in a minimal smoker." J.A. 455. *See also* J.A. 451, 461; S.A. 8-11; Deposition at 47-65.

None of the three experts designated by petitioners on the causation issue disagreed with any aspect of Teitelbaum's methodology, or with his application of the methodology, or with the types of data that he relied upon.[19] Indeed, these experts used

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[18] Teitelbaum traveled to Atlanta, where he conducted a full-scale examination in a physician's office outside the presence of any lawyers. J.A. 449; S.A. 3-4, 21. *But see* Pet. Br. 36 (asserting without any evidence that Teitelbaum simply met Joiner "at the lawyers' office").

[19] The only expert for petitioners who made even passing reference to Dr. Teitelbaum's testimony stated that he had not reviewed Teitelbaum's deposition

the very same methodology as Teitelbaum — they looked at the same sources of information as Teitelbaum, and engaged in inductive reasoning to assess the likelihood that these substances had promoted Joiner's cancer — and differed with Teitelbaum only as to the conclusion they reached using this methodology.[20] Only petitioners' *lawyers* were critical of Dr. Teitelbaum's methodology, asserting in legal memoranda that it was unscientific.[21]

Dr. Schecter.[22] Arnold Schecter, M.D., M.P.H., likewise enjoys "a national reputation." App. 8a. He has been a tenured medical professor since 1979 and is one of the few American physicians who works full time doing research on the toxic effects of PCBs, furans and dioxins. J.A. 399. He has published over 100 peer-reviewed papers on this subject since 1981. J.A. 399, 424-42. Although Schecter concentrates almost entirely on research and teaching, he also sees patients and has served as a consultant to the EPA, the U.S. Public Health Service, the National Academy of

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and was "not really" "aware of his opinions." S.A. 59 (Waddell). Further, even after Joiner filed, with his opposition to the summary judgment motion, an affidavit by Teitelbaum laying out his methodology in greater detail, petitioners still made no effort to impeach the validity of Teitelbaum's methodology, or of its application, with additional testimony from their own experts.

[20] *See* S.A. 54-56 (Bailey) (relying on a review of Joiner's deposition and medical records, and of scientific literature); Deposition of William J. Waddell, M.D., at 12, 14-15, 17, 24-25, 30-33, 54-55, 80-81, 100, 105-06 (same); Deposition of Dr. Philip Cole, at 8, 11, 15, 94-95] (same). See also note 57, *infra*.

[21] Those lay criticisms are repeated in this Court. For example, petitioners suggest that Dr. Teitelbaum's opinion hinged on the two mouse studies by Anderson, et al. that were singled out for criticism by the district court. Pet. Br. 9; *see also* App. 58a-61a. In fact, when asked by petitioners in his deposition on what studies he based his conclusion, Teitelbaum stated that he relied on "volumes of articles on PCBs that I've collected and read over the years." S.A. 5. As Exhibit 12-A to his deposition, Teitelbaum included a list of twenty-two studies that were particularly important (and also included photocopies of the articles, *see* Exhibit 12-C), at least four of which reviewed data on humans. *See* S.A. 3, 23-26.

[22] Teitelbaum and Schecter reached their conclusions independently of each other. S.A. 5 (Teitelbaum); S.A. 28 (Schecter).

Sciences, and the World Health Organization with respect to their study of PCBs, furans and dioxins. J.A. 399-401, 414-15; *see also* S.A. 126-27.

In reaching an opinion with respect to whether petitioners' products contributed to Joiner's development of lung cancer at age 37, Schecter testified, without contradiction, that he "followed the methodology usually and generally followed by physicians and scientists." J.A. 403. Applying this methodology, he interviewed Joiner and analyzed each of the following: Joiner's deposition testimony and affidavit; Joiner's medical records; a videotape of the conditions under which Joiner worked while repairing electrical transformers containing petitioners' products; the results of PCB testing done on these transformers; the relevant available scientific literature on the toxic effects of the PCBs, furans and dioxins contained in petitioners' products; the scientific literature demonstrating that these substances tend to accumulate in the lung, the target organ here; and the deposition testimony of the other experts in the case. Applying this methodology, Schecter eliminated other potential causes of the early onset of Joiner's lung cancer based on biographical data showing that Joiner had not been exposed to other substances known to promote the development of initiated cancer cells. J.A. 403-07; S.A. 33-34, 36.

Based on his analysis, Dr. Schecter concluded that it was likely that "Robert Joiner's exposure to PCB contaminated mineral oil dielectric fluid served as a promotional effect on his lung cancer cells, probably initiated by cigarette exposure years before and caused him to contract lung cancer at the very young age of 37. But for Robert Joiner's exposure to PCB contaminated mineral oil dielectric fluid I believe that he would not now be suffering from lung cancer." J.A. 403.

None of petitioners' experts disagreed with any aspect of Schecter's methodology, or with his application of the methodology, or with the types of data that he relied upon.[23]

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[23] Petitioners' experts perfunctorily mentioned having read Schecter's deposition, S.A. 55 (Bailey); S.A. 59 (Waddell); S.A. 61 (Cole); and/or limited their criticisms to Schecter's "opinions" or "interpretations of the analytical data."

Instead, petitioners' experts simply used this same basic methodology to reach opposite conclusions. See note 20, *supra*. Only petitioners' *lawyers* were critical of Dr. Schecter's methodology, asserting that it was unscientific.[24]

D. The Motion for Summary Judgment

Petitioners moved for summary judgment on two basic grounds. First, they claimed that the testimony of Drs. Teitelbaum and Schecter was inadmissible under Fed. R. Evid. 702 because these experts had assumed that Joiner was exposed to furans and dioxin when, in fact, the record did not support that assumption.[25]

S.A. 59 (Waddell); S.A. 74 (Brown). Indeed, one of petitioners' experts, when asked if he had "an opinion as to the[] scientific validity" of Schecter's publications on the subject of PCBs, testified that "I think the data is probably about as good as could be obtained," that Schecter has "worked with a lot of analytical chemists that are well regarded," and that he could not "think of any specific cases where" he disagreed with Schecter's analysis. S.A. 65-66 (Hamilton).

[24] Those lay criticisms are repeated in this Court. As with Dr. Teitelbaum, *see* note 21, *supra*, petitioners claim that Schecter's testimony hinged on the same two mouse studies by Anderson, et al. on which the district court focused its attention. Pet. 5-6 (citing J.A. 110-11). But the cited pages do not support the contention that Schecter relied in any way on these particular studies; instead, Schecter states that in evaluating the promotional effects of PCBs, furans and dioxins, he relied on a number of human and animal studies. J.A. 110-11. Petitioners' experts agreed that it is an entirely appropriate methodology to take into account animal studies with respect to this issue. *See, e.g.*, S.A. 57-58 (Waddell) (animal studies are necessary "because it's unethical to do to humans" what is done to the animals); S.A. 58-59 (Waddell) ("the purpose of studies on animals is to be able to get information which can or may be extrapolated in humans" and "[t]he method is accepted . . . and is appropriate and proper").

Petitioners further suggest that Schecter inappropriately ignored a test result that purported to show that Joiner received only an average dose of PCBs. Pet. Br. 6. But Schecter filed an affidavit on this subject establishing that because of methodological flaws with that test, no reasonable scientist could rely on such a test to estimate Joiner's level of exposure. J.A. 407-08. Subsequent to the filing of this affidavit, petitioners made no effort to strike this portion of the affidavit as inadmissible or otherwise to controvert the affidavit.

[25] Defendants' Joint Memorandum in Support of Summary Judgment ("SJ Memo"), filed Dec. 8, 1993, at 23-25.

Second, petitioners claimed that although Joiner was concededly exposed to PCBs, there was no evidence that he had absorbed a significant dose[26] and, in any event, that the opinions of Teitelbaum and Schecter were not "credible"[27] because several of the epidemiological and animal studies that they had looked at assertedly did not support the conclusion that petitioners' products had probably contributed to Joiner's development of lung cancer.[28] Because petitioners' experts had not offered any criticism of the methodology used by Teitelbaum and Schecter, petitioners were forced to rely on a description and critique of several of the studies offered by petitioners' lawyers.[29] Offering their own analysis of the underlying scientific data, the lawyers asserted that the conclusions reached by Teitelbaum and Schecter "are not based on credible scientific evidence and are therefore 'speculative'."[30]

In response, Joiner filed a detailed affidavit by Teitelbaum, the bulk of which explicitly rebutted the assertions of petitioners' lawyers, J.A. 456-70, and an affidavit by Schecter setting out his methodology and conclusions in more detail. J.A. 403-10. Even at this juncture, petitioners filed no expert testimony in support of their lawyers' assertions; nor did petitioners file a motion *in limine* to rule inadmissible anything in the affidavits. Instead, they simply filed another memorandum of *law* making further assertions that the conclusions reached by Joiner's experts were incorrect.[31]

E. The District Court's Grant of Summary Judgment

Three separate rulings of the district court are relevant at this juncture, as is an understanding of what the court *did not* hold:

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[26] *Id.* at 25-28.

[27] *Id.* at 10.

[28] *Id.* at 29-38.

[29] *Id.* at 29-32, 36-37.

[30] *Id.* at 3.

[31] Reply Memorandum filed February 28, 1994, at 7-11, 17-18.

1. What the District Court Held. First, the district court agreed with petitioners that there was no evidence in the record that Joiner was exposed to furans or dioxins. App. 44a-51a.

Second, building on this ruling, the district court held that "the opinions of [Joiner's] experts do not fit the facts of the case because the opinions are inextricably bound up with the experts' assumptions that Joiner was exposed to furans and dioxins." App. 53a; *see also* App. 57a (opining that Joiner "failed to show a genuine dispute over whether furans and dioxins were in the PCBs to which Joiner was exposed" so that his experts' testimony "manifestly does not fit the facts of this case, and is therefore inadmissible" under Fed. R. Evid. 702). This, the district court stated, was the "strongest" argument for refusing to admit the experts' causation testimony. App. 53a.

Third, and finally, the district court held that even if Joiner's experts "had not made unfounded assumptions about furans and dioxins," App. 58a, but instead had predicated their opinions solely on the theory that PCBs alone had promoted the development of Joiner's lung cancer:

> Defendants still persuade the court that Plaintiffs' expert testimony would not be admissible. Defendants do this by attacking the conclusions that Plaintiffs' experts draw from the studies they cite.

App. 58a. After agreeing with the analysis in petitioners' memoranda of law concerning the proper conclusions to be drawn from several of the studies considered by Joiner's experts, *see* App. 58a-67a, the district court held that it was "persuaded" that "the studies simply do not support the experts' position that PCBs *more probably than not* promoted Joiner's lung cancer." App. 67a (emphasis in original).

2. What the District Court Did Not Hold. Because the district court's rulings were predicated on its initial finding that there was no evidence in the record that Joiner was exposed to furans or dioxins, App. 44a-51a, the district court never addressed — one way or the other — the issue of whether the testimony of Joiners'

experts that PCBs, furans and/or dioxins, *in combination*, had promoted Joiner's lung cancer, was admissible. In other words, the district court did not hold that the experts' *actual* testimony was inadmissible under *Daubert* if, as the experts assumed, Joiner was exposed to all three substances. The district court simply regarded that testimony irrelevant, based on its initial holding that there was no evidence that Joiner was exposed to furans or dioxins. It only ruled inadmissible what Joiner's experts might *hypothetically* have testified to in light of its first ruling: that PCBs *alone* promoted Joiner's lung cancer.[32]

F. The Court of Appeals' Rulings in Reversing the District Court's Grant of Summary Judgment

Since the parties' briefs were in agreement on the applicable standard of review of summary judgment rulings involving the admissibility of expert testimony,[33] the standard of review was only

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[32] That point is made unambiguously clear by the district court's statement that one reason the "Yusho study" had "no utility for Plaintiffs' purposes" is that "the persons studied were exposed to furans and dioxins." App. 67a. Thus, the Solicitor General's suggestion that this Court could reverse the court of appeals and direct it to affirm the district court's grant of summary judgment, *see* SG Br. 24-30, suffers from a basic conceptual error: given the court of appeals' holding — uncontested in this Court — that the record does contain evidence of exposure to furans and dioxins, see pp. 16, 21, 31-33, *infra*, and the absence of any ruling by the district court that the expert testimony respecting the causative impact of the three carcinogenic substances in combination is inadmissible, there is nothing left to affirm. Not surprisingly, therefore, petitioners themselves seek only a remand of the case for further proceedings, *see* Pet. 14 n.4, and argue not that the district court's judgment must be affirmed, but only that "the judgment of the Court of Appeals should be reversed." Pet. Br. 50.

[33] *See* Brief of Appellants, No. 94-9131, 11th Cir., at 4-5; Brief of Appellees at 8-9 & n.9. *See also* Reply Brief of Appellants at 6 n.3 (noting parties' agreement "that if a district court uses a proper construction of the Federal Rules of Evidence in ruling on admissibility issues, its rulings are subject to abuse-of-discretion review" and that defendants did not contest the analysis in Joiner's opening brief that "*de novo* review applies in determining whether the district court applied an erroneous construction of the Federal Rule of Evidence" and that "abuse-of-discretion review is conducted more strictly, and with greater scrutiny, where necessary to ensure that the district court does not substitute its judgment for that of a jury.").

briefly discussed at the beginning of the court of appeals' opinion. App. 4a-5a.[34] The court of appeals reversed the district court on the following grounds:

1. The District Court's Assertion of the Absence of Exposure to Furans and Dioxins, and the Consequent Lack of "Fit"

With respect to the district court's first ruling, the Eleventh Circuit held, on the basis of its review of the record, that "a genuine dispute . . . exists over whether furans and dioxins could have been present in the dielectric fluid." App. 14a-15a. Based on its reversal of the first ruling, which was the sole predicate of the district court's second ruling concerning a lack of "fit," the Eleventh Circuit then held that "the testimony of plaintiffs' experts was erroneously excluded and summary judgment should not have been granted." App. 16a.[35]

[34] The standard of review was set out in the opinion of Judge Barkett, and the special concurrence of Judge Birch fully accepted this analysis. App. 16a-17a. Judge Smith, in his opinion dissenting on other grounds, also accepted Judge Barkett's analysis, although he endeavored to set forth "a more precise explanation of the standard of review," using somewhat different "review terminology." App. 18a-19a.

[35] As with the standard of review, the grounds for reversing the district court's first and second rulings were set forth in Judge Barkett's opinion, and Judge Birch's special concurrence did not disagree with this analysis in any respect. *See* App. 16a-17a. Judge Smith, in dissent, indicated that he would uphold the district court's first ruling (and, on that basis, the second ruling as well). He conceded that there *was* record evidence of exposure to furans and dioxins, but would have upheld the district court because (he thought) plaintiffs had not adequately called that evidence to the attention of the district court. *See* App. 22a-23a. Petitioners did not seek certiorari with respect to the majority's decision that there is a genuine issue of material fact as to whether Joiner was exposed to furans and dioxins.

2. The District Court's Holding That, Even if Predicated Solely on Exposure to PCBs, the Conclusions of Joiner's Experts Were Not Supported by the Studies They Cited

Addressing the district court's analysis of whether the expert opinions were admissible if based on exposure to PCBs *alone*, the Eleventh Circuit held that the district court had erred as a matter of law in its construction of Fed. R. Evid. 702.[36] After noting that the testimony of Joiner's experts — that they had "each utilized scientifically reliable methods and procedures in gathering and assimilating all of the relevant information in forming their respective opinions" — was *uncontroverted* by any testimony from scientists, App. 10a-11a, and that the district court had declared only that the experts' "conclusions" were unreliable, the Eleventh Circuit held that the district court had committed the very legal error against which this Court had cautioned in *Daubert*:

> "The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate."

App. 13a (quoting *Daubert*, 509 U.S. at 595).[37]

G. The Petition for Rehearing and Petition for Certiorari

Following the reversal of all three of the district court's rulings, petitioners filed a petition for rehearing. Petitioners did not seek

[36] The Eleventh Circuit did not explain why it addressed this issue, given that its first ruling alone required reversal. Perhaps it reasoned that the issue might recur at a later stage of the litigation (e.g., if petitioners asked the district court to instruct the jury that if it found no exposure to furans and dioxins, then it must rule for petitioners). In this respect, the Eleventh Circuit observed that "it does not necessarily follow that each expert's opinion that PCB caused Joiner's cancer was contingent upon his exposure to furans or dioxins," so that it could be regarded as "immaterial whether there were furans and dioxins in the fluid." App. 14a.

[37] The court of appeals went on to hold that, in light of petitioners' failure to introduce any expert testimony challenging the reliability of the methodology of Joiner's experts, "PCB exposure only" expert testimony would be admissible, creating "a genuine factual dispute as to whether PCBs alone can cause cancer," and making this issue "inappropriate for summary judgment." App. 14a.

rehearing on the panel's fact-specific analysis of the district court's first two rulings. They did seek rehearing on the panel's decision on the third ruling, arguing that the panel had too narrowly construed the scope of a district court's "gatekeeping" authority under *Daubert*.[38] Further, petitioners objected to a portion of the court of appeals' description in its opinion of the standard of review for admissibility rulings.[39] Rehearing was denied without dissent. App. 32a-33a.

Subsequently, petitioners sought and obtained an extended stay of the issuance of the mandate based on the argument that "[a] petition for certiorari would present a substantial question for the Supreme Court, that is, there is a conflict among the circuits as to whether the 'particularly stringent' standard of review should apply to district court *Daubert* rulings."[40] In this filing, petitioners made no suggestion that their *other* rehearing issue, concerning the panel's Rule 702 reversal of the district court for excluding testimony based on its determination that the experts' *conclusions* were unreliable, might merit review in this Court. They omitted that question from their petition for certiorari and presented only their objection to the panel's standard of review. Pet. i. "Once the proper standard of review is decided," petitioners assured this Court, the case could simply be remanded, so that this Court "need not itself reexamine the record." Pet. 14 n.4.

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[38] Suggestion of Rehearing En Banc of Appellees, No. 94-9131, 11th Cir., at 8-15. The argument made in this portion of the petition for rehearing parallels the argument that petitioners now seek to have this Court address. *See* Pet. Br. 45-50.

[39] Suggestion of Rehearing En Banc of Appellees at 4-8.

[40] Defendants-Appellees' Motion to Extend Stay of Issuance of Mandate, No. 94-9131, 11th Cir., at 1-2.

SUMMARY OF ARGUMENT

In view of the precise holdings of the district court and the grounds for reversal by the court of appeals, the issues discussed by petitioners should be resolved as follows.

I. The court of appeals correctly described the appropriate standard of review at the outset of its opinion: *de novo* review of whether, on this record, a genuine issue of material fact existed regarding Joiner's exposure to furans and/or dioxins; plenary review of whether the district court erred in its construction of a Federal Rule of Evidence; and, if the district court's ruling was free of legal error, abuse-of-discretion review of the ultimate decision respecting admissibility — with a "hard look" to see if an abuse of discretion has occurred in cases where the ruling determines whether the case will be summarily taken from the trier of fact. As we show in Part II of our argument, the last aspect of the standard of review (respecting abuse of discretion) was never reached in deciding this case, because the district court's rulings all were reversed for errors of law. Thus, the question presented in this case relates to a dictum in the opinion below. Nevertheless, as the Court has granted certiorari to review that dictum, we explain why it should be upheld. Properly understood, the "hard look" dictum does not prescribe a different standard of review, but merely expresses a commonsense approach to the allocation of scarce judicial resources: that in applying the *same* standard of review, courts will look more closely at challenged rulings that are outcome determinative and, therefore, prejudicial if erroneous.

II. Even if this Court does not agree with the "hard look" dictum, the judgment below should still be affirmed, because the dictum was not applied in this case and did not affect the disposition below. The decisive ruling in this case related to the district court's conclusion, under Rule 56 of the Federal Rules of Civil Procedure, that no record evidence existed to support the assumption of Joiner's experts that Joiner was exposed to furans and dioxins. Once the court of appeals reversed that threshold ruling — which dealt with a factbound question of the application of Rule 56 that is not before this Court on the present petition —

the district court's subsidiary rulings as to the admissibility of expert testimony under Rule 702 became unavailable as grounds for upholding the district court.

The second ruling of the court below — that, with respect to *hypothetical* testimony from Joiner's experts that exposure to PCBs alone caused his lung cancer, the district court erred as a matter of law in its construction of Rule 702 by testing for reliability of the experts' conclusions rather than their methodology — applied the plenary standard of review for error of law. District courts do not have "discretion" to misinterpret the Federal Rules of Evidence. As petitioners did not seek certiorari to review the court of appeals' legal ruling construing Rule 702, that ruling remains in place.

III. If this Court decides to consider petitioners' challenge to the legal correctness of the distinction between methodology and conclusion that the court of appeals observed — despite the absence of a question presented on this point — it will discover that petitioners' argument rests on a series of mistaken assertions about the Eleventh Circuit's analysis and the record in this case, as well as a failure to recognize that the very claim petitioners assert here was advanced in *Daubert* and rejected by this Court.

ARGUMENT

I. THE JUDGMENT BELOW SHOULD BE AFFIRMED BECAUSE THE DECISION OF THE ELEVENTH CIRCUIT WAS CORRECT IN ITS DESCRIPTION OF THE APPROPRIATE STANDARD OF REVIEW

As explained in Part II of this brief, the court of appeals never engaged in abuse-of-discretion review of the district court rulings as to the admissibility of expert testimony. Instead, the district court was reversed for legal error, both on the issue of exposure to furans and dioxins and on the independent issue of the proper construction of Rule 702. Abuse-of-discretion review was mentioned only when the court began its opinion (as appellate courts often do) by reciting the review standards that govern in the particular area. App. 4a-5a; see also pp. 15-16 & nn. 33 and 34,

supra. Thus, the question presented in this Court pertains to a dictum in the opinion below. Nonetheless, we begin by showing that the Eleventh Circuit's recital of the review standards in this area was correct.

A. The Eleventh Circuit Correctly Reviewed the Record *De Novo* to Determine If a Genuine Issue of Material Fact Existed With Respect to Exposure to Furans and Dioxins

Citing this Court's decision in *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986), the court of appeals first stated that a grant of summary judgment is reviewed *de novo*; that "[s]ummary judgment is appropriate when there is no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law" under Fed. R. Civ. P. 56(c); and that "[t]he moving party bears the burden of showing that there is no issue of material fact." App. 4a. Petitioners do not challenge this standard. As the *amicus* brief filed by the Solicitor General ("SG Br.") recognizes, this standard of review was proper. SG Br. 24.

The court of appeals applied this standard to the district court's holding (see p. 16, *supra*) that on this record there was no genuine issue of material fact as to whether Joiner was exposed to furans and dioxins. Under this standard, the court of appeals conducted its own *de novo* review of the record and determined that there *was* a triable issue of exposure to furans and dioxins.

This ruling — which petitioners do not challenge here — necessarily disposed as well of the district court's second ruling that because furans and dioxins were not present, the experts' testimony about the causative effect of PCBs *in combination* with furans and dioxins does not "fit" the case and on that ground is inadmissible. App. 14a-16a.

B. The Eleventh Circuit Correctly Engaged in Plenary Review of Whether the District Court Erred in Its Construction of a Federal Rule of Evidence

In its summary of the standard of review, the court of appeals stated that "[t]o the extent that the district court's ruling turns on an interpretation of a Federal Rule of Evidence, our review is plenary."

App. 5a (citing *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 749 (3d Cir. 1994)). This analysis, which petitioners do not challenge, was obviously correct under this Court's past rulings. *See, e.g., Daubert*, 509 U.S. at 587 ("We interpret the legislatively-enacted Federal Rules of Evidence as we would any statute."); *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 163 (1988) ("Because the Federal Rules of Evidence are a legislative enactment, we turn to the 'traditional tools of statutory construction' in order to construe their provisions.") (citation omitted). .

The court of appeals then proceeded to engage in plenary review of the construction of Rule 702 relied on by the district court when it held that if, hypothetically, Joiner's experts had assumed exposure to PCBs alone, testimony of probable causation would not be admissible. The district court had based its ruling on the fact that it was "persuade[d]" by petitioners' attack on "the conclusions that Plaintiffs' experts draw from the studies they cite," App. 58a — that "the studies simply do not support the experts' position that PCBs *more probably than not* promoted Joiner's lung cancer." App. 67a (emphasis in original). The Eleventh Circuit reversed on the ground that Rule 702 did not authorize the district court to address such matters. It noted that under Rule 702, as construed in *Daubert*, "the district court's focus is a narrow one and does not encompass deciding which expert's conclusions are better reasoned or more appealing," or making "independent scientific judgments on the basis of individual studies." App. 11a. The court of appeals quoted this critical passage in the *Daubert* opinion:

> "The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate."

App. 13a (quoting *Daubert*, 509 U.S. at 595).

Following an analysis of the district court's opinion, *see* App. 11a-13a, the court of appeals stated:

> Instead of viewing the bases of an expert's opinion as a whole to screen out mere speculation, the district court assessed only a portion of the studies relied upon by each of the Joiners' experts, and then *excluded the testimony because it drew different conclusions from the research* than did each of the experts. Ultimately, the court should satisfy itself as to the legal reliability of proffered expert testimony, leaving the jury to decide the correctness of competing expert opinions.

App. 13a (emphasis added). Thus, the Eleventh Circuit's holding on this ground was predicated on its finding that the district court had made a basic legal error: it focused on the experts' conclusions, not on their methodology.[41] As Judge Birch amplified in his concurring opinion, the District Court failed to understand that "[t]he *sufficiency* of the evidence and the *weight* of the evidence . . . are beyond the scope of the *Daubert* analysis. Whether the conclusions advanced from the stated premises in fact follow and the persuasiveness of these conclusions in the ultimate resolution of competing opinions, are questions appropriately left to the finder of fact." App. 16a-17a.

Once the court of appeals had held that the district court erred under *Daubert* in focusing not on whether the *methodology* used by Joiner's experts was valid, but instead on whether their *conclusions* were correct, at minimum a remand on the issue for further analysis under the proper legal standard was necessary. Joiner, however, had urged the court to go further, arguing that there was "no need for a remand" given that Joiner's experts were "concededly qualified and concededly employed a valid, indeed standard, methodology."[42] After concluding, on a review of the record, that

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[41] The district court's holding, to which this ruling applied, bears recalling:

> Assuming that Plaintiffs' experts had not made unfounded assumptions about furans and dioxins, Defendants still persuade the court that Plaintiffs' expert testimony would not be admissible. Defendants do this by attacking the conclusions that Plaintiffs' experts draw from the studies they cite.

App. 58a.

[42] Brief of Appellants, No. 94-9131, 11th Cir., at 6. *See also id.* at 21 (arguing that because petitioners "submitted no expert testimony responding" to the affidavits filed by Joiner's experts, "[t]he qualifications of, and methodologies employed by, Drs. Teitelbaum and Schecter remained unchallenged. As a matter of law, the district court erred in holding their

these concessions had in fact been made by petitioners, *see* App. 8a, 10a-11a, the court of appeals ruled that "PCB exposure only" expert testimony would be admissible, creating "a genuine factual dispute as to whether PCBs alone can cause cancer" and making this issue, as well, "inappropriate for summary judgment." App. 14a.

C. Although Not Pertinent To Any of Its Rulings, the Eleventh Circuit Was Correct That, in Reviewing District Court Evidentiary Rulings Made Under a Proper Construction of the Federal Rules of Evidence, a District Court Should Be Reversed Only for an Abuse of Discretion

The court of appeals further observed, in its introductory discussion of the standard of review, that "[a] district court's ruling on the admissibility of evidence is reviewed for abuse of discretion." App. 4a. More precisely, given the prior point, if the district court does not commit an error of law in construing the relevant Federal Rule of Evidence, *then* its ruling is reviewed for abuse of discretion.[43]

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testimony inadmissible."); Reply Brief of Appellants at 10-13 (summarizing petitioners' concessions on methodology issue).

[43] Because the discussion in the court of appeals' decision of the abuse-of-discretion standard of review was a dictum that it never actually *applied* in deciding this case, it is difficult be certain what the court below *meant* by the dictum. Further, because the court's mention of this review standard was never applied to a concrete record, anything that this Court says in this case about the scope of a district court's discretion and the standard of review thereof will necessarily be abstract and hypothetical, carrying all the risks generally associated with advisory opinions. Compare *Koon v. United States*, 116 S. Ct. 2035, 2043 (1996); *First Options of Chicago, Inc. v. Kaplan*, 514 U.S. 938, 115 S. Ct. 1920, 1922-23 (1995), in both of which the court of appeals had actually applied the standard of review that was examined by this Court. In that context, we wish to flag for the Court's attention three matters that are not posed by resolution of this case but that might otherwise *inadvertently* be resolved in a general discussion of the scope of discretion accorded district courts.

First, in its *Daubert* decision, this Court stated that "[m]any factors will bear on the inquiry" into whether an expert has followed the scientific method, but did "not presume to set out a definitive checklist or test," and emphasized that "[t]he

The petition for certiorari contended that the circuits were "completely split" the issue of whether evidentiary rulings are

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inquiry envisioned by Rule 702 is . . . a flexible one." 509 U.S. at 593-94. Petitioners and their *amici* understand this to mean that district courts are free to do essentially whatever they want, free of appellate oversight, in selecting the factors that they will deploy on a case-by-case basis to judge the scientific method. Although this case does not present the issue, we understand the Court to have meant something quite different: that given the enormous range of scientific disciplines that are the subject of federal litigation and hence are governed by *Daubert*, what constitutes "good science" may vary between fields, requiring the application of different criteria in different fields. What factors may, must, or must not be applied in judging the validity of a scientific methodology in a given field would appear to involve issues of law that will ultimately be defined by the appellate courts, subject in turn to abuse-of-discretion review in the application of those factors. *See, e.g., Koon*, 116 S. Ct. at 2047. For example, if a district court chose to determine the admissibility of psychiatric testimony by using only the four factors specifically mentioned by this Court in *Daubert*, and no others, it might well conclude that all such testimony is inadmissible in all cases. (It would appear that the reliability of psychiatric testimony is not "falsifiable," nor does it have a quantifiable "error rate".) Appellate courts presumably must have authority to declare that consideration of such factors is not permissible in determining whether an expert's methodology is scientific in the field of psychiatry.

Second, as the Solicitor General briefly touches on (SG Br. 19-21), appellate courts must be able, over time, to develop *categorical* rules of admission or exclusion that can define and delimit the scope of district court discretion with respect to particular methodologies that are routinely litigated and become widely accepted as being either valid or invalid. At least some role in this area on the part of appellate courts seems essential to ensuring a basic level of consistency (rather than randomness) in the administration of justice in like cases.

Third, even where there may *not* exist a consensus built up through experience with respect to the validity of a particular methodology, there may be instances in which the methodology arises so frequently in federal litigation that it is imperative that a uniform answer as to its admissibility be declared. Imagine, for example, that half of the district judges nationwide are ruling that a particular new forensic technique that is often outcome determinative is sufficiently reliable to be admissible, while the rest of the judges are routinely excluding all evidence based on the technique. It would be intolerable to have the fate of vast numbers of cases turn entirely on the identity of the judges to whom they are assigned, without the opportunity for appellate reconciliation.

Our discussion in text addresses the reviewability of exercises of discretion that do not implicate any of the foregoing considerations.

properly reviewed for "abuse of discretion" as opposed to "manifest error." Pet. 6-10. Following the grant of certiorari, petitioners now accept the view set forth in Joiner's opposition to certiorari (at 8-13) that *all* circuits apply an abuse-of-discretion standard, although some judges occasionally use older "manifest error" language to express precisely the same level of deference to district courts. *See* Pet. Br. 24-26.[44] The dissenting judge below agreed on the "deference to the trial court's admissibility determinations" that exists under *Daubert*, App. 20a n.1, although he also offered "a more precise explanation of the standard of review," using "terminology that is firmly established in the jurisprudence of this and other circuits." App. 18a-19a. The *amici* supporting petitioners who address the standard-of-review issue are likewise in accord. Thus, there appears to be broad agreement that the court below did not err in this dictum.

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[44] *See, e.g.*, *United States v. Rahm*, 993 F.2d 1405, 1409-10 (9th Cir. 1993) (observing that "general adoption of the 'abuse of discretion' characterization would bring this area into line with the rest of our law of evidence. . . . The 'manifest error' characterization apparently emanates from a Supreme Court decision preceding the judiciary's efforts to settle on a limited number of review characterizations. *See Salem v. United States Lines Co.*, 370 U.S. 31, 35 (1962). There appears to be no practical difference between the two verbal formulae, so their vestigial co-existence serves no obvious purpose. Accordingly, it would be sensible to settle upon a uniform practice of characterizing our standard of review as 'abuse of discretion' and abiding by it in all future cases") (citations omitted); *United States v. Boney*, 977 F.2d 624, 628 n.2 (D.C. Cir. 1992) (the two standards amount to "the same test"); *Phillips Oil Co. v. OKC Corp.*, 812 F.2d 265, 280 & n.32 (5th Cir.), *cert. denied*, 484 U.S. 851 (1987) ("We construe these various statements of the standard of review to be harmonious.").

Even if "manifest error" were a different standard, petitioners and their *amici* agree that "abuse of discretion" — the standard recited by the court of appeals below — is the correct one.

D. Although Not Pertinent to Any of Its Rulings in This Case, the Eleventh Circuit Was Also Correct in Endorsing the Third Circuit's Practice of Taking a "Hard Look" at Whether a District Court Has Abused Its Discretion in Rulings Excluding Expert Testimony Where the Rulings May Entirely Preclude the Trier of Fact From Considering a Litigant's Case

Finally, in its brief overview of the proper review standard, the Eleventh Circuit endorsed the view taken in Judge Becker's *Paoli* decision that appellate judges should take a "hard look" at certain decisions relating to the exclusion of expert testimony. App. 4a-5a (citing *Paoli*, 35 F.3d at 750). Petitioners suggest that this is a new, *different* standard of review for expert testimony, and they suggest that the judges on the court below were divided on whether a "hard look" is warranted in such cases, stating that "Judge Smith in dissent reasoned that there should be 'deference to the trial court's admissibility determinations.'" Pet. Br. 16 (quoting App. 20a n.1). Petitioners are doubly wrong: this is not a different standard, and Judge Smith did not disagree with the majority on this point.

Judge Smith, in fact, clearly stated his understanding that in reviewing for abuse of discretion, the majority's requirement that appellate judges take a "hard look" in appropriate circumstances *does not* involve a different standard of review. Elaborating on the brief summary of this point by the majority, he noted: "In applying a 'particularly stringent' review, we do not change the threshold of review, but conduct a searching review of the record (i.e., take a 'hard look') while maintaining the proper standard of review." App. 18a (citing *Paoli*, 35 F.3d at 749-50). Indeed, in the very footnote quoted by petitioners, in which Judge Smith cited case law from "circuits addressing *Daubert* [that] have shown similar deference to the trial court's admissibility determinations," Judge Smith cited the *Paoli* case itself, approvingly, as embodying such deference. He described *Paoli* as involving simply "a 'hard look' at trial court's exercising its discretion." App. 20a-21a n.1.

Our reading of the decision below with respect to the standard of review is simply that, in a world of limited judicial resources, appellate courts will devote more time and attention — i.e., a "hard look" — to determining *whether* a district court has abused its discretion in admissibility rulings that are outcome determinative of

the case. So construed, Judge Becker's analysis, and its endorsement by the court of appeals below, is hardly objectionable. It flows from the commonsense perspective that appellate judges should spend their time on the cases where there is the greatest danger that an abuse of discretion has occurred: e.g., in a case where a trial judge's discretionary decision on admissibility has determined the outcome of the entire litigation, not in a case where the evidence excluded was cumulative.

Obviously, it makes little sense for appellate judges to take the time to engage in a hard look at the record of a case with respect to rulings where the asserted error had little to do with the outcome of the case. As the *Paoli* decision observed, "the likelihood of finding an abuse of discretion is affected by the importance of the district court's decision to the outcome of the case and the effect it will have on important rights." *Id.* at 750. This analysis was supported by reference to the doctrine permitting reversal only for prejudicial error, and by analogy to this Court's decision in *Mathews v. Eldridge*, 424 U.S. 319, 334 (1976), recognizing that "the procedural safeguards required by due process increase as the importance of the decision being made increases." *Paoli*, 35 F.3d at 750.[45] Of course, as Judge Smith observed below, devoting extra resources to determining whether an abuse of discretion has occurred on a given record does not *change* the standard of review.

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[45] From this perspective, Judge Becker's statement that a "hard look" should be accorded only in cases where the admissibility ruling is outcome determinative is nothing more than a "concession to the shortness of life." *Reeve v. Dennett*, 11 N.E. 938, 944 (1887) (Holmes, J.). In a world of unlimited resources, all appellate judges would: (1) take a hard look at each and every evidentiary ruling on which error is asserted, determining whether an abuse of discretion has occurred, and then (2) apply the doctrine of prejudicial error to determine whether the disadvantaged party is entitled to relief. As petitioners themselves recognize, Pet. Br. 39-40, we do not live in such a world. It is eminently rational for appellate judges to devote less time to the review of admissibility decisions that are unlikely to have had much to do with the outcome of the case, thereby conserving scarce time and energy for the review of important admissibility rulings. Thus, viewed in context, the "hard look" is merely a doctrine permitting the efficient allocation of judicial resources.

The concept of reserving extra judicial time and attention for important admissibility decisions, and less time for trivial ones, need not inevitably cut in favor of the admission of evidence. As one *amicus* brief filed in support of petitioners observes, "[i]n suggesting that 'a hard look' should be taken, appellate courts have expressed their concern about trial court decisions *to admit or exclude*."[46] As this *amicus* brief points out, in a leading decision written by Judge Higginbotham, the Fifth Circuit has noted that although it "adhere[s] to the deferential standard for review of decisions regarding the admission of testimony by experts," appellate judges "will turn to [their review] task with a sharp eye, particularly in those instances, hopefully few, where the record makes it evident that the decision to receive expert testimony was simply tossed off to the jury under a 'let it all in' philosophy." *In re Air Crash Disaster Near New Orleans*, 795 F.2d 1230, 1234 (5th Cir. 1986). This approach has been followed in other circuits as well.[47]

Whether one speaks of a "hard look" or of a "sharp eye," the message is the same: without applying a *different* standard of review, and within the accepted context of reviewing evidentiary rulings for abuse of discretion, appellate judges may reasonably reserve the bulk of their time and attention for evidentiary issues that matter to the outcome of litigation, whether those issues involve the exclusion of evidence (addressed by *Paoli*) or the admission of evidence (addressed by *In re Air Crash Disaster*). Upholding the use of Judge Becker's "hard look" at whether an abuse of discretion has occurred, where the result of a ruling excluding evidence is important because it is the basis for a grant of summary judgment against a plaintiff, does *not* constitute a rejection of Judge Higginbotham's concern for an equally hard look by appellate courts with respect to potentially outcome

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[46] Brief of *Amici Curiae*, The Product Liability Advisory Council, Inc., The National Association of Manufacturers, and Medmarc, in Support of Petitioners ("PLAC Br.") at 7 (emphasis added).

[47] *See Joy v. Bell Helicopter Textron, Inc.*, 999 F.2d 549, 569-70 (D.C. Cir. 1993); *United States v. DiDomenico*, 985 F.2d 1159, 1163 (2d Cir. 1993).

determinative rulings in favor of the admissibility of evidence (where, but for the admissibility ruling, a grant of summary judgment in favor of defendant might be warranted). Whether a comparable "hard look" for abuse of discretion is warranted in the latter circumstance is a question that can, and should, be deferred until an appropriate case is presented.[48]

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[48] There are two possible grounds for devoting greater appellate resources to reviewing the exclusion of critical evidence than its admission. The first is the preference for the admissibility of relevant evidence that Congress embedded in the plain language of the Federal Rules of Evidence. Fed. R. Evid. 402 creates a presumption that "all relevant evidence is admissible," so that it can be excluded only if "provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority." This Court has noted the "liberal thrust of the Federal Rules" and, in particular, how Rules 702 through 705 follow a "general approach of relaxing the traditional barriers to 'opinion' testimony." *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988); *see also* App. 4a (noting "preference for admissibility" underlying Federal Rules of Evidence). One of petitioners' *amici* makes a worthwhile point that Rule 402 and "the liberal policies underlying the Rules" should not be double or triple counted with respect to the standard of review. *See* Brief of the Chamber of Commerce of the United States as *Amicus Curiae* in Support of Petitioners at 26-27. Presumably, however, the explicit statutory presumption in favor of admitting relevant evidence justifies devoting at least *some* additional appellate resources to deciding whether specific rules authorize the exclusion of evidence that meets the threshold test of relevancy.

Another possible distinction between the two situations is that the exclusion of important, relevant evidence, unlike its admission, can impair the full realization of a significant constitutional value — the Seventh Amendment guarantee of a jury trial. *See, e.g., Paoli*, 35 F.3d at 750 n.20. For example, even though it is not outcome determinative of a case, appellate courts have long engaged in "a more searching inquiry" of a grant of a new trial on weight-of-the-evidence grounds than of a denial, "to protect the litigants' right to jury trial." *Langevine v. District of Columbia*, 106 F.3d 1018, 1023 (D.C. Cir. 1997) (quoting *Lind v. Schenley Indus., Inc.*, 278 F.2d 79, 90 (3d Cir.) (en banc), *cert. denied*, 364 U.S. 835 (1960)).

II. THE ELEVENTH CIRCUIT'S JUDGMENT SHOULD BE AFFIRMED EVEN IF THIS COURT DISAGREES WITH THE STANDARD OF REVIEW RESPECTING ABUSE OF DISCRETION ARTICULATED BELOW

As already noted, the court of appeals' reference to the abuse-of-discretion standard of review, and the "hard look" that at times is called for under that standard, was only a dictum that did not turn out to be relevant to the disposition of this case. The court of appeals' rulings were reached on threshold grounds — legal error by the district court — that mooted any question of abuse of discretion. It follows that even if the Court does not agree with the standard of review recited in dictum below, the judgment of the court of appeals still must be affirmed.

A. Petitioners Did Not Seek Review of the Eleventh Circuit's Holding That the Record Contains Evidence of Joiner's Exposure to Furans and Dioxins — a Holding That is Unaffected by the "Hard Look" Reference And That Is Dispositive

Affirmance of the court of appeals is required, first and foremost, because the key ruling of the district court — that there was no genuine issue of material fact concerning whether Joiner was exposed to furans and dioxins — constituted legal error. Based on this threshold legal error, the district court held that because Joiner's experts assumed exposure to furans and dioxins, their testimony did not "fit" the facts of the case, and must therefore be excluded under Rule 702. See p. 14, *supra*.

Once the Eleventh Circuit held, on *de novo* review, that the record did present a genuine issue concerning Joiner's exposure to furans and dioxins, it was required to reverse the district court's Rule 702 holding that the testimony of Joiner's experts did not "fit" the facts, because that ruling was entirely premised on an erroneous view of the record. It did so. See p. 17, *supra*.[49]

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[49] We note that, at this narrow juncture, one can describe the court of appeals' opinion as based on a finding that the district court abused its discretion — in that it is always an abuse of discretion for a district court to rule evidence

A grant of certiorari on the factbound issue of whether the court of appeals was right in its dispositive determination concerning furans and dioxins would have been highly unusual,[50] and petitioners elected not to ask this Court to review that issue. Indeed, with respect to this issue they did not even seek rehearing in the Eleventh Circuit. It is therefore clear at this juncture "that respondents have adequately raised a factual issue concerning Robert Joiner's exposure to furans and dioxins." SG Br. 24. It follows that the Eleventh Circuit's decision reversing the *only* district court ground for excluding expert testimony premised on

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inadmissible based on a clearly incorrect, and pivotal, assumption about the record facts. But petitioners do not contend that *this* holding of the court of appeals was in any way affected by the "hard look" approach endorsed by the panel of which petitioners complain. As is clear from the Solicitor General's analysis, this holding is proper under any conception of the abuse-of-discretion review standard:

> [T]he court of appeals was entitled to review for clear errors of fact or law affecting the district court's ruling. Because it reversed the trial court's holding that there was no genuine issue of fact concerning respondent's exposure to furans or dioxins, the court of appeals could properly conclude that it should also reverse the admissibility ruling to the extent that it relied on the observation that the proffered opinions were "inextricably bound up with the experts' assumption that Joiner was exposed to furans and dioxins." Pet. App. 53a; see *id.* at 53a-57a. The ruling that the proffered testimony "manifestly does not fit the facts of this case" (*id.* at 57a) was based on a view of the facts that was clearly incorrect in light of the appellate court's independent ruling on summary judgment, and it therefore cannot remain a permissible ground for exclusion under Rule 702.

SG Br. 25.

[50] *See generally* Robert L. Stern, et al., *Supreme Court Practice* § 4.14, at 189-91 (7th ed. 1993). Obtaining certiorari on this issue would have been especially difficult given the evidence from petitioners' own experts, and from Joiner's experts in testimony which petitioners did not attack as inadmissible, showing that during Joiner's relevant work period, furans and dioxins were routinely present in the commercial PCB mixtures that contaminated the mineral oil transformers with which Joiner worked. See note 4, *supra*. Petitioners' discussion ignores this evidence and focuses on asserted gaps in the record concerning the precise mechanics by which the furans and dioxins that are routinely present are generated. *See* Pet. Br. 7, 9, 13 n.13.

exposure to *a combination* of these carcinogenic substances cannot be disturbed on this record, thus requiring that the judgment of the court of appeals be affirmed.

As we have already observed, see note 32, *supra*, there is a basic conceptual error in the Solicitor General's suggestion (not advanced by petitioners) that this Court might enter a judgment affirming the district court's grant of summary judgment. Such a result would only be possible if the district court had ruled, in the alternative, that even if the testimony of Joiner's experts had *correctly* assumed exposure to PCBs, furans and dioxins, such testimony would be inadmissible because the district court was "not persuaded" that the studies on PCBs, furans and dioxins supported the particular conclusions of the experts. But the district court made no such holding and, indeed, given the concession of petitioners' experts that furans and dioxins are more carcinogenic than PCBs, see note 5, *supra*, it could hardly have done so. Instead, the district court simply held that in its view the studies *on PCBs alone* did not support the conclusions of Joiner's experts. Once the court of appeals held that the record supported a finding of Joiner's exposure to all three substances, there was simply nothing left to affirm.

B. Petitioners Did Not Seek Review of the Eleventh Circuit's Holding That the District Court Committed Legal Error in Its Construction of Rule 702 — a Holding Also Unaffected by the "Hard Look" Reference

Affirmance of the court of appeals is also required because the only holding of the district court whose reversal is challenged in this Court — that if the testimony of Joiner's experts were construed as asserting causation based on exposure to PCBs alone, it would be inadmissible under Rule 702 — was unaffected by the Eleventh Circuit's reference to a "hard look" in abuse-of-discretion review of admissibility rulings.

The court of appeals addressed the district court's third ruling (perhaps because it might eventually arise in the case, if the jury determined as a matter of fact that Joiner was *not* exposed to furans and dioxins, see note 36, *supra*). It reversed because it found an error of law: an incorrect construction of the Rule 702 reliability test articulated by this Court in *Daubert*. The district court quite

explicitly said that it was rejecting the testimony of Joiner's experts because the *conclusion* they reached was unreliable. The court of appeals understood this Court's decision in *Daubert* to have held that only the methodology, not the conclusion, is to be tested for reliability. See pp. 17, 22-23, *supra*. Thus, in the view of the court of appeals, the district court's ruling was infected by legal error. And legal error, of course, is subject to plenary review. (This is true whether or not the court of appeals was *correct* in its understanding of *Daubert*, an issue petitioners chose not to present in their petition.)

* * *

In sum, none of the rulings below turned on any review of the district court's rulings for abuse of discretion, much less a "hard look" at whether the district court abused its discretion. On that basis, the judgment of the Eleventh Circuit should be affirmed even if this Court disagrees with the abuse-of-discretion standard of review as it was articulated in dictum below.

III. PETITIONERS' CLAIM THAT THE TESTIMONY OF JOINER'S EXPERTS IS INADMISSIBLE UNDER RULE 702 IS WITHOUT MERIT

Petitioners plainly recognize that the court of appeals' last-discussed ruling was predicated on the view that there was an error of law in the district court's Rule 702 analysis. Thus, despite not having presented the question in their petition for certiorari, they now argue at the close of their merits brief that the court of appeals committed legal error of its own in its construction of Rule 702 and, in particular, misconceived the line between methodology and conclusion. *See* Pet. Br. 46-50.[51] Various *amici* representing the

[51] Citing primarily the court of appeals' discussion of whether the record contained evidence of Joiner's exposure to furans and dioxins, petitioners also complain at this juncture that "whenever it believed information relevant to admissibility was lacking," the court "put the burden of producing it on petitioners." Pet. Br. 45 (citing App. 15a, Pet. Br. 36-37). As explained earlier, petitioners' inability to convince the court of appeals that no genuine issue existed with respect to the presence of furans and dioxins involved only a garden-

interests of companies and individuals who are often named as defendants in tort litigation join petitioners in an effort to persuade this Court to collapse the methodology/conclusion distinction and empower district courts to assess the reliability of the *conclusions* reached by experts who are applying indisputably correct *methodologies* — under the guise of assessing whether there is a "logical" or "analytical" gap between methodology and conclusion. We address these belatedly asserted Rule 702 issues on the chance, however remote, that this Court might choose to reach them.[52]

variety record analysis under Rule 56, not an evidentiary issue under Rule 702. See p. 21, *supra*. Petitioners also cite here the court of appeals' observation that the district court had ruled on the basis of what various studies said without having *obtained and read the studies*. App. 13a n.9. But this observation placed no burden on petitioners; under Fed. R. Evid. 705 the burden would have been on Joiner to supply any copies (beyond the 22 studies already provided by Teitelbaum, see note 21, *supra*) had the district court requested them. *See, e.g.*, *Ambrosini v. Labarraque*, 966 F.2d 1464, 1468-69 (D.C. Cir. 1992).

[52] In their petition for certiorari, petitioners posed only the standard-of-review issue and stated that "[o]nce the proper standard of appellate review is decided, this Court need not itself reexamine the record," but could simply order that "'the case is remanded for further proceedings consistent with this opinion.'" *Id.* at 14 n.4 (quoting disposition of *Daubert*, 509 U.S. at 598). Once review was granted, however, petitioners designated 520 pages of the record below and proceeded to revive the very Rule 702 arguments on the proper scope of this Court's *Daubert* analysis that they had raised on rehearing but not in the petition for certiorari. See pp. 17-18, *supra*. *But see* Sup. Ct. R. 14.1(a) ("Only the questions set out in the petition, or fairly included therein, will be considered by the Court"). *See also Izumi v. U.S. Philips Corp.*, 510 U.S. 27, 30-32 (1993); *Yee v. City of Escondido*, 503 U.S. 519, 535-36 (1992); *Irvine v. California*, 347 U.S. 128, 129-30 (1954) (plurality opinion of Jackson, J.). *See, e.g.*, *First Options of Chicago, Inc. v. Kaplan*, 514 U.S. 938, 115 S.Ct. 1920, 1926 (1995) ("Finally, First Options argues that, even if we rule against it on the standard-of-review questions, we nonetheless should hold that the Court of Appeals erred in its ultimate conclusion that the merits of the Kaplan/First Options dispute were not arbitrable. This factbound issue is beyond the scope of the questions we agreed to review.").

A. The Eleventh Circuit Did Not Rule the Testimony of Joiner's Experts Admissible Based Merely on Their Credentials

Petitioners claim error in the court of appeals' supposed holding that Rule 702 can be satisfied by the mere fact that a party's experts are exceptionally qualified. Pet. Br. 46-47 (citing App. 11a). The court below held no such thing. In the passage cited by petitioners, the court merely noted that "the extensive experience and specialized expertise of each of these experts *augment* the reliability of their reasoning and methodology," and have "*some* bearing on the determination of the reliability of the underlying reasoning or methodology." App. 11a (emphasis added). In *Daubert*, this Court noted that "[m]any factors will bear on the inquiry" under Rule 702 into the reliability of an expert's methodology, and it did "not presume to set out a definitive checklist or test," choosing instead simply to list four illustrative factors. 509 U.S. at 592. The court below cited precedent from two other circuits taking into account an expert's exceptional qualifications as *one* factor in evaluating methodology under Rule 702, and none of the cases cited by petitioners suggests that it is legal error to do so.

More fundamentally, petitioners fail to acknowledge that consideration of the qualifications of Joiner's experts came only *after* the court of appeals had cited its primary reason for concluding that Rule 702 had been satisfied here. The uncontradicted record evidence, it noted, established that each of Joiner's experts "utilized scientifically reliable methods and procedures in gathering and assimilating all of the relevant information in forming their respective opinions," that these methods are generally accepted, and that "defendants do not challenge these claims." App. 10a-11a.

Petitioners assert that this holding is "[q]uite unaccountabl[e]," Pet. Br. 37, and claim that they introduced evidence from their experts "explicitly" challenging the methodology of Joiner's experts. Pet. Br. 38. But that simply is not the case. As Joiner

established in his briefing below without contradiction,[53] petitioners' *experts* never attacked the methodology used by Joiner's experts, see notes 19 & 23, *supra*, and they actually employed the same methodology to reach their own conclusions. See note 20, *supra*. The testimony cited by petitioners, Pet Br. 38, simply reveals that petitioners' experts reached *different conclusions* respecting causation using *the same methodology*.[54]

Of course, petitioners also cite at this juncture the fact that their lawyers made assertions in their briefs challenging the methodology of Joiner's experts. Pet. Br. 38 (citing J.A. 387-88, 390-91, 515, 517). Indeed, it was the *lawyers'* challenges that the district court professed to find persuasive. App. 58a. But "[l]egal memoranda and oral argument, in the summary-judgment context, are not evidence." *Smith v. Mack Trucks, Inc.*, 505 F.2d 1248, 1249 (9th Cir. 1974) (per curiam). There is already enough reason to worry that district judges will be tempted to play "amateur scientist" in carrying out their role under Rule 702, *see Daubert*, 509 U.S. at 600-01 (Rehnquist, C.J., joined by Stevens, J., concurring in part and dissenting in part), without deputizing lawyers to serve as

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[53] Brief of Appellants, No. 94-9131, 11th Cir., at 16-21; Reply Brief of Appellants at 13. In light of the description in these pages of the uncontradicted record evidence establishing the validity of the methodology employed by Joiner's experts, the court of appeals' observation that "defendants do not challenge these claims," App. 11a, is completely understandable.

[54] On this record, the case therefore fell under the doctrine — which had long before been adopted by the Eleventh Circuit and which petitioners do not challenge here — that where "experts on both sides rel[y] on essentially the same diagnostic methodology" and "differ[] solely on the conclusions they dr[a]w from test results and other information," an expert's testimony is to be admitted even if it is "controversial in its conclusions." *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1535 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984). *See, e.g., Cella v. United States*, 998 F.2d 418, 426 (7th Cir. 1993); *Ambrosini, supra*, 966 F.2d at 1467-69; *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1111 & n. 9 (5th Cir. 1991) (en banc), *cert. denied*, 503 U.S. 912 (1992); *Hines v. Conrail*, 926 F.2d 262, 274 (3d Cir. 1991); *Wells v. Ortho Pharmaceutical Corp.*, 788 F.2d 741, 744-45 & n.8 (11th Cir.), *cert. denied*, 479 U.S. 950 (1986). Joiner made this point to the Eleventh Circuit without contradiction from petitioners. *See* Brief of Appellants, No. 94-9131, 11th Cir., at 12.

authoritative expositors of the scientific method, whose opinions on that subject can be adopted by district courts in the face of uniform contrary testimony from professional scientists.

B. The Eleventh Circuit Did Not Err in Its Analysis That the District Court Had Committed Legal Error By Focusing Solely on the Experts' Conclusions, Not on Their Methodology

Petitioners also claim error in the court of appeals' construction of Rule 702 in that the court "treated *Daubert*'s requirement of scientific methodology at such a superficial level as to leave it meaningless — calling for no more than the invocation of scientific materials." Pet. Br. 47. The court of appeals, petitioners assert, "essentially held that if an expert cites conventional scientific authorities, the expert has satisfied the requirement of scientific methodology, no matter what the authorities actually say, and what steps are missing between the citations and the conclusion." Pet. Br. 48. If *Daubert* "made anything clear," they argue, an expert may not "escape methodological scrutiny simply by invoking a black box called science." *Id.* One answer to this argument can be found in the record; another can be found in the *Daubert* decision itself.

1. The Record

A dispositive answer to petitioners' objection, closely tied to the record of this case, is that the court of appeals did *not* find Rule 702 satisfied merely because Joiner's experts cited some scientific materials. Rather, as we have already discussed, Joiner's experts laid out in detail, both in their depositions and in Rule 56(e) affidavits answering the criticisms advanced by petitioners' lawyers, the multi-step methodology they had applied to reach a conclusion as to whether or not petitioners' products likely contributed to the development of Joiner's lung cancer at age 37. See pp. 8-12, *supra*. Reviewing this uncontroverted record evidence, the court of appeals first noted that both Dr. Teitelbaum and Dr. Schecter had conducted a standard, detailed occupational medical assessment of Joiner, analyzing his physical condition,

medical and family history, exposure to potential carcinogens, and the like. App. 9a-10a. The court then noted that "*[i]n addition*, each doctor utilized numerous scientific studies and authorities," App. 10a (emphasis added), and that "defendants [did] not challenge" the testimony of Joiner's experts that their overall methodology was scientifically valid. App. 10a-11a. Nowhere did the court of appeals remotely suggest that Rule 702 was satisfied by some abstract "invocation of scientific materials." Pet. Br. 47.

Petitioners' effort to undermine the uncontroverted record showing that Joiner's experts applied a valid methodology is unavailing. Declining to discuss *the evidence* on methodology, petitioners instead challenge the court of appeals' statement that "[o]pinions of any kind are derived from individual pieces of evidence, each of which by itself might not be conclusive, but when viewed in their entirety are the building blocks of a perfectly reasonable conclusion." App. 12a. Petitioners assert that this view is a "fallacy." Pet. Br. 49 (citation omitted).

According to petitioners' lawyers, because no epidemiological study has been performed on PCBs proving, at a "statistically significant," near-certainty level, that PCBs cause small-cell lung cancer (the precise type of lung cancer that Joiner developed), the testimony of Joiner's experts based on the body of evidence that *is* available cannot be valid. Pet. Br. 48. On this ground, petitioners would preclude reliance on the human epidemiological evidence reflecting substantial increases in cancer (including lung cancer) among those exposed to PCBs, see notes 2 & 3, *supra*, as well as the animal studies that corroborate and strengthen the implications of that evidence. See *id.* The assertions of petitioners' lawyers would require dismissing Joiner's claims despite the fact that the scientific consensus is in *his* favor, given that federal health authorities believe that it is "probable" that PCBs cause cancer in humans, including lung cancer. See note 3, *supra*.

But, contrary to the beliefs of petitioners' lawyers, the scientific method includes protocols for addressing the *likelihood* of causation in the absence of unequivocally dispositive evidence. As the EPA has observed in its official analysis of the proper methodology for deciding the likelihood that substances cause

cancer, it is rare that a carcinogen will be detected to a level of 95 percent "statistical significance" in a human epidemiological study; indeed, experts called by Joiner and petitioners alike agreed that the type of epidemiological study that petitioners erect as their ideal would be (quite conveniently for petitioners) effectively impossible to conduct.[55]

The assertion of petitioners' lawyers that the court of appeals erred in admitting the testimony of Joiners' experts because it is a "fallacy" for scientists to evaluate the full range of available data on a potential carcinogen and then reach a conclusion based on those data, using their judgment and experience, is obviously baseless. Analysis of the overall weight of available data is the very methodology used by the EPA (and its consultants, including Teitelbaum and Schecter) in assessing the likelihood of carcinogenic danger. The EPA's current guidelines on the subject state:

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[55] *See* EPA, *Guidelines for Carcinogen Risk Assessment*, 51 FED. REG. 33992, 33995-96 (Sept. 24, 1986) ("epidemiologic studies are inherently capable of detecting only comparatively large increases in the relative risk of cancer. Negative results from such studies cannot prove the absence of carcinogenic action."). *See also* Office of Science and Technology Policy, *Chemical Carcinogens: A Review of the Science and its Associated Principles*, 50 FED. REG. 10372, 10378 (1985) ("A high-quality negative epidemiological study, while useful, cannot prove the absence of an association"); S.A. 59 (Waddell) (concession by one of petitioners' experts that a controlled epidemiological study on humans that would "give them a dose" of PCBs "[t]o see whether they get lung cancer " is ruled out because it is "unethical to give anyone something to see if it produces a carcinoma . . . that's not a proper kind of experiment"); S.A. 20 (Teitelbaum) ("Q. Now, to be specific to this case, is there any study that you know of anywhere in humans that indicate that small-cell, being specific to this diagnosis, lung cancer was caused by PCBs?"; "A. No. It's an impossible research question to investigate, I think, in the first place, and in the second place, there is no such study."); S.A. 17 (Teitelbaum) ("if you wanted to study PCBs in electricians at age 35, I haven't done the calculations, but you'd need millions, I think, millions of exposed people to get a statistically significant finding, or millions of person years anyway").

> Evidence of possible carcinogenicity in humans comes primarily from two sources: long-term animal tests and epidemiologic investigations. Results from these studies are supplemented with available information from short-term tests pharmacokinetic studies, comparative metabolism studies, structure-activity relationships, and other relevant toxicologic studies. ***The question of how likely an agent is to be a human carcinogen should be answered in the framework of a weight-of-evidence judgment.*** Judgments about the weight of evidence involve considerations of the quality and adequacy of the data and the kinds and consistency of responses induced by a suspect carcinogen. There are three major steps to characterizing the weight of evidence for carcinogenicity in humans: (1) Characterization of the evidence from human studies and from animal studies individually, (2) combination of the characterizations of these two types of data into an indication of the overall weight of evidence for human carcinogenicity, and (3) evaluation of all supporting information to determine if the overall weight of evidence should be modified.

EPA, *supra* note 55, at 33996 (emphasis added).[56] It is the same methodology that was used by *petitioners'* experts.[57] Indeed, it is

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[56] Analysis of a full range of data on suspected toxins to determine their probable health effects on humans is, of course, accepted practice among a variety of federal health authorities. *See generally* Brief of *Amici Curiae* American Society of Law, Medicine and Ethics, *et al*, in Support of Petitioners, *Daubert*, No. 92-102, at 11-20 (surveying the scientific practice in this respect).

[57] As one of petitioners' experts, Dr. Bailey, put it: "I've just reviewed a lot of literature and come to some conclusions." S.A. 56. *See also* S.A. 58-59 (Waddell) ("the procedure is to get all the information we can," including animal data); S.A. 64-65 (Hamilton) (GE scientist had no expertise on PCBs before 1981; based on just one year of reviewing the literature, he had become informed enough to write a federal regulatory body arguing that it was wrong in its conclusion that PCBs are a probable human carcinogen); S.A. 62 (Cole), and Deposition of Dr. Philip Cole at 26, 88 (admits that EPA is an "august body" on the subject of "human carcinogen[s] for the lung," but simply disagrees with EPA

a fundamental part of the scientific method generally.[58]

Beyond Joiner's compelling showing on the basis of science that the assertions of petitioners' lawyers are groundless, those assertions fail the test of common sense under established principles of evidence law. It is a "simple fact[] of evidentiary life"

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that "PCB exposure is a cause of cancer in human beings"; his own conclusion is that the "body of evidence . . . doesn't give the slightest inkling that these things cause human cancer."). Of course, the fact that petitioners' experts reviewed the same data as the EPA and reached a different conclusion does not mean that their testimony is inadmissible. Such disagreement in a world of complexity and uncertainty is hardly unusual. *See, e.g.*, Laurence H. Tribe, *Trial by Mathematics: Precision and Ritual in the Legal Process*, 84 HARV. L. REV. 1329, 1348 (1971) ("Different people, of course, would typically assign different subjective probabilities to the same propositions — but that is as it must be, unless the propositions in question are unusually simple.").

[58] For example, an *amicus* brief filed in *Daubert* by a number of prominent scientists addressed this issue specifically in the context of the science of epidemiology, observing that "'[a]ll scientific work is incomplete — whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer on us a freedom to ignore the knowledge we already have, or to postpone action that it appears to demand at a given time.'" Brief *Amici Curiae* of Physicians, Scientists and Historians of Science in Support of Petitioners ("Gould Br."), *Daubert*, No. 92-102, at 9 (quoting Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 PROCEEDINGS OF THE ROYAL SOCIETY OF MEDICINE 295, 299-300 (1965)). "As a consequence," these scientists noted, "those who seek in science the immutable truth they find lacking in law are apt to be disappointed:

> One notable similarity [between law and epidemiology] is the dependence of both fields upon subjective judgments.
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> In the end, a quality which lawyers should understand better than any — judiciousness — matters more than any. Scientists use both deductive and inductive inference to sustain the momentum of a continuing process of research. . . . The courts of law, and the courts of application, use inference to reach decisions about what action to take. Those decisions often cannot rest on certitudes, most especially when population risks are converted into individual risks."

Id. at 9-10 (quoting Susser, *Rules of Inference in Epidemiology*, in 6 REGULATORY TOXICOLOGY AND PHARMACOLOGY 116, 128 (1986)).

that "individual pieces of evidence, insufficient in themselves to prove a point, may in cumulation prove it. The sum of an evidentiary presentation may be greater than its constituent parts." *Bourjaily v. United States*, 483 U.S. 171, 179-80 (1987).[59]

Moreover, to require the type of statistical certainty insisted on by petitioners would significantly alter state substantive law in the guise of applying a federal rule of evidence, without any indication from Congress of an intent to displace state law in such a sweeping manner. As Professor Nesson has observed, a "requirement that proof of causation be made exclusively according to the standards and methodology of statistical science" would be "tantamount to institutionalizing an objectively determinable probability greater than .5 for cases in which proof of causation involves a disputed supposition about the working of nature." Charles Nesson, *Agent Orange Meets the Blue Bus: Factfinding at the Frontier of Knowledge*, 66 B.U. L. REV. 521, 538-39 (1986).[60] This point has

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[59] *See also* Tribe, *supra* note 57, at 1350 ("Few categories of evidence indeed could ever be ruled admissible if each category had to stand on its own, unaided by the process of cumulating information that characterizes the way any rational person uses evidence to reach conclusions.").

[60] Of course, a State might opt for a substantive rule of law withholding compensation in the absence of "statistically significant" evidence even though, as Nesson warns, such a rule would "substantially insulate[] companies from the consequences of negligently exposing persons to toxins," giving them "an incentive to ignore even known risks" and "to use what resources and political muscle they have to obstruct or skew any epidemiological study that might prove statistically that their conduct caused injury." *Id.* at 537. Some of petitioners' *amici* apparently favor such a rule, but they make no showing either that Georgia has adopted such a rule (it has not) or that in enacting the Federal Rules of Evidence in 1975, Congress purported to change tort law in this manner. Indeed, Congress interrupted the Rules Enabling Act process and recrafted the Federal Rules of Evidence itself "to assure a *minimum* of tampering with state substantive rights," thus policing "the limitation specified in the second sentence of the 1934 Rules Enabling Act against abridging substantive rights." Olin Guy Wellborn III, *The Federal Rules of Evidence and the Application of State Law in the Federal Courts*, 55 TEX. L. REV. 371, 401 (1977) (emphasis added). *See also* 22 Charles Alan Wright & Kenneth W. Graham, *Federal Practice and Procedure: Evidence* § 5006, at 106, 108 (1978). Rule 702 would, in any event, be a particularly unlikely congressional vehicle for tort reform given that, as one of petitioners'

been made widely in the literature, by both legal scholars and scientists.[61]

2. The *Daubert* Decision

There is a further, more fundamental answer to petitioners' argument. Petitioners proceed as if this Court has never considered the issue of how much, if at all, a federal court should delve into the substance of an expert's particular conclusions in deciding whether the expert's testimony constitutes "scientific knowledge" within the meaning of Rule 702. Thus, quoting selectively from *Daubert*, petitioners state that the term "scientific knowledge" cannot involve "'subjective belief or unsupported speculation,'" Pet. Br. 47 (quoting 509 U.S. at 590), and that "'under the Rules the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.'" Pet. Br. 48 (quoting 509 U.S. at 589). Based on these phrases, petitioners claim to find in *Daubert* the following principle: the requirement that an expert's testimony constitute "scientific knowledge" under Rule 702 "includes as a minimum that *conclusions be logically supported by premises*." Pet. Br. 48 (emphasis added). That is, the conclusions of a qualified expert witness are inadmissible under Rule 702 where a lay judge finds that "there is an 'analytic gap'" between those conclusions and the scientific materials" that is

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amici notes, "Rule 702 received little attention" in Congress. Brief of *Amicus Curiae* The Washington Legal Foundation in Support of Petitioners at 14 n.10.

[61] *See, e.g.*, Michael D. Green, *Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of* Agent Orange *and Bendectin Litigation*, 86 NW. U. L. REV. 643, 667-68, 682-94, 697 (1992); V. Brannigan, V. Bier, and C. Berg, *Risk, Statistical Inference, and the Law of Evidence: The Use of Epidemiological Data in Toxic Tort Cases*, in 12 RISK ANALYSIS 343 (1992); D.H. Kaye, *Is Proof of Statistical Significance Relevant?*, 61 WASH. L. REV. 1333 (1986); Steve Gold, *Causation in Toxic Torts: Burdens of Proof, Standards of Persuasion, and Statistical Evidence*, 96 YALE L.J. 376 (1986); Neil B. Cohen, *Confidence and Probability: Burdens of Persuasion in a World of Imperfect Knowledge*, 60 N.Y.U. L. REV. 385, 413-14 (1985).

"simply 'too wide'."[62]

According to petitioners, under Rule 702 it is not enough that an expert is applying a concededly valid methodology to reach a conclusion on a disputed scientific issue. Instead, the conclusion *itself* must "be logically supported," without "too wide" an "analytic gap" between the conclusion and the underlying data. In other words, to be admissible, the district court must believe that the conclusion is correct. Indeed, this has been petitioners' position from the start of this litigation, in urging that the district court exclude the testimony of Joiner's experts based on their view that the *conclusions* of the experts simply *did not follow* from the studies they cited. See pp. 12-13, *supra*. The district court accepted this construction of Rule 702, holding as follows:

> Assuming that Plaintiffs' experts had not made unfounded assumptions about furans and dioxins, Defendants still persuade the court that Plaintiffs' expert testimony would not be admissible. Defendants do this by attacking the conclusions that Plaintiffs' experts draw from the studies they cite.

App. 58a.

The legitimacy of a construction of Rule 702 permitting such analysis was exhaustively explored by the parties and *amici*, and was rejected by this Court, in *Daubert*. There, the central contention of respondent with respect to the proper disposition of the case was that an overwhelming consensus existed among experts who had studied Bendectin that the drug was safe and could never cause birth defects and that, because the plaintiffs' experts had reached a contrary *conclusion*, their testimony must be inadmissible.[63] As to the distinction between methodology and

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[62] SG Br. 26 (quoting App. 67a (quoting *Turpin v. Merrell Dow Pharmaceuticals, Inc*, 959 F.2d 1349, 1360 (6th Cir.), *cert. denied*, 506 U.S. 826 (1992)); *see also* Pet. Br. 4. Significantly, the Solicitor General does not argue that there *was* an analytical gap in this case, only that the district court's belief that such a gap existed is entitled to deference. *See* SG Br. 30 (entertaining assumption that "reasonable minds might differ on that issue").

[63] *See, e.g.*, Respondent's Brief in Opposition, *Daubert*, No. 92-102, at 1-4 (asserting "overwhelming" and "universally recognized" nature of evidence

conclusion that had been proposed by plaintiffs, respondent in *Daubert* argued that it was "hard to see how to derive [plaintiffs'] distinction from Rule 702."[64]

A number of the *amici* in *Daubert* responded that the distinction between methodology and conclusion is inherent in the concept of "scientific knowledge" and thus necessary for analysis under Rule 702. In particular, leading scientists and scientific organizations explained the nature of scientific inquiry and "scientific knowledge," and urged this Court to construe Rule 702 as focusing on a scientist's methodology, not on his or her conclusions. For example, a brief filed by historians of science including Prof. Stephen Jay Gould noted that "[i]nstead of directly evaluating the methodology of the research on which plaintiffs' experts relied, the Ninth Circuit began with those experts' conclusions and worked backwards."[65] Two of the nation's leading scientific organizations likewise explained, in a passage ultimately quoted by this Court, that: "Science is not an encyclopedic body of knowledge about the universe. Instead, it represents a *process* for proposing and refining

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favoring respondent with respect to the conclusion that Bendectin does not cause limb defects); Brief for Respondent at 5, 11 (referring to the "massive body of uniform scientific research," and "overwhelming body of data" contradicting conclusion of plaintiffs' experts).

[64] Brief for Respondent at 16 n.9. Beyond its assertion that no such distinction could be made under Rule 702, respondent in *Daubert* attempted to muddy the methodology/conclusion distinction through what might be termed a "litigation-by-thesaurus" strategy, by inventing ambiguous phrases to describe the Rule 702 test which lumped together the concepts of methodology and conclusion, in an effort to obscure the distinction between the two. *See, e.g.*, Brief for Respondent, *Daubert*, No. 92-102, at 9 (suggesting "adequate foundation" requirement); *id.* at 10 ("reliable foundation" test); *id.* at 12 ("conclusions that are validated" test); *id.* at 17 ("natural 'accepted-standards-for-validation' meaning" for Rule 702); *id.* at 21 ("'foundation' requirement"); id. at 22 (judge should "screen evidence based on its substance"); *id.* ("foundational inquiry" test); *id.* at 24 ("foundation filter"); *id.* at 26 ("adequate foundation under accepted standards for validation" test); *id.* at 27 ("'accepted standards' foundational requirement"); *id.* at 27 n.18 ("foundational rule"); *id.* at 33 ("proper materials"/"used in reasonable fashion" test).

[65] Gould Br., *supra* note 58, at 5 (citing Opposition to Cert. at 3).

theoretical explanations about the world that are subject to further testing and refinement."[66]

Similarly, a brief submitted by a leading authority on federal evidence, as part of a scholarly foundation's long-term project on scientific evidence, argued that under Rule 702 "courts should focus on determining whether the expert engaged in recognized forms of scientific practice in reaching his or her conclusion," that is, "whether the scientific claim . . . is the product of a recognized form of scientific inquiry," an inquiry that "does not require that the judge understand or undertake an extensive examination of the hypotheses being put forth" or mean "that a federal judge in ruling on admissibility should evaluate the *content* of the scientific evidence."[67]

In its *Daubert* decision, this Court accepted the view of these and other authorities and rejected the argument of the respondent that there was no basis for distinguishing under Rule 702 between the *methodology* relied on by an expert and his or her *conclusions*. In particular, this Court agreed that science is defined by its process, not its product: Science is not "'an encyclopedic body of knowledge about the universe,'" but rather "'a *process* for proposing and refining theoretical explanations about the world,'" and that "[t]he adjective 'scientific' implies a grounding in the methods and procedures of science." 509 U.S. at 590. Therefore, the Court concluded that "to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method," *id.*; that Rule 702 concerns "the scientific validity of [proposed testimony's] underlying principles," *id.* at 595 n.12; that "[i]n a

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[66] Brief for the American Association for the Advancement of Science and the National Academy of Sciences as *Amici Curiae* in Support of Respondent, at 7-8 (emphasis in original) (quoted in *Daubert*, 509 U.S. at 590).

[67] Brief of the Carnegie Commission on Science, Technology, and Government as *Amici Curiae* in Support of Neither Party (co-authored by Prof. Margaret A. Berger), *Daubert*, No. 92-102, at 5, 7-8, 10 (emphasis in original). *See also Daubert*, 509 U.S. at 600-01 (Rehnquist, C.J., joined by Stevens, J., concurring in part and dissenting in part) (expressing concern with any construction of Rule 702 that "imposes on [federal judges] either the obligation or the authority to become amateur scientists").

case involving scientific evidence, *evidentiary reliability* will be based upon *scientific validity*," *id.* at 591 n.9; and that "[p]ertinent evidence based on scientifically valid principles will satisfy" Rule 702. *Id.* at 597.

In sum, as this Court construed Rule 702 in *Daubert*, as long as an expert's *methodology* is valid, his or her *conclusion* is admissible, because it is the product of a scientific process. Under Rule 702, this Court emphasized:

> The focus, of course, must be solely on principles and methodology, not on the conclusions they generate.

509 U.S. at 595.

Petitioners and their *amici* are forced to variously ignore, paraphrase or misquote this passage in the process of arguing that Rule 702 should be construed so that a federal court may only admit an expert's testimony if it appears to the court that the expert's conclusion is *correct*.[68] These verbal somersaults are no more impressive than the similar linguistic efforts made by the respondent in *Daubert*. See note 64, *supra*. The *Daubert* Court recognized that its ruling might result in the admission of *conclusions* that were decidedly against the mainstream — although that is certainly not *this* case[69] — but regarded

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[68] Nowhere in their argument that the court of appeals misconstrued Rule 702 do petitioners even mention this critical passage in the *Daubert* decision. *See* Pet. Br. 46-50. Most of petitioners' *amici* simply ignore it as well; the *amici* who do paraphrase or quote the passage do so in a misleading (even ridiculous) manner. *See, e.g.*, Brief of Chemical Manufacturers Association as *Amicus Curiae* in Support of Petitioners, at 15 (describing *Daubert* as holding that "under Rule 702, a court must focus on the reasoning process and methodology through which they were developed and validated, *not just the conclusions* themselves") (emphasis added); Brief of the Dow Chemical Company as *Amicus Curiae* in Support of Petitioners, at 15 (arguing that under Rule 702, "the essence of what *Daubert* is all about" is whether "the purported bases for an expert's opinion actually support *that opinion*") (emphasis added).

[69] The conclusions of Joiner's experts in this case that PCBs likely promoted the development of Joiner's lung cancer are hardly "controversial," given the conclusion of the federal government and the World Health Organization that PCBs "probably" cause cancer in humans, including lung cancer, and given petitioner Monsanto's own experience. See note 3 and page 4, *supra*.

"apprehension" over this prospect as reflecting undue pessimism

> about the capabilities of the jury, and of the adversary system generally. Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.

509 U.S. at 595-96.

In its decision below, the court of appeals faithfully complied with this resolution of the dividing line between the admissibility and the weight of expert scientific testimony, and this Court's admonition that the focus of analysis under Rule 702 must be solely on an expert's methodology, not the expert's conclusion. App. 6a-8a, 13a, 16a-17a. That message has been heeded not just by the court below, but the federal appellate courts generally. *See, e.g.*, *Ambrosini v. Labarraque*, 101 F.3d 129, 133-34, 140 (D.C. Cir. 1996), *cert. dismissed*, 117 S. Ct. 1572 (1997); *In re Joint E. & S. Dist. Asbestos Litigation*, 52 F.3d 1124, 1132-33 (2d Cir. 1995); *Claar v. Burlington N. R.R.*, 29 F.3d 499, 501-03 (9th Cir. 1994); *United States v. Chischilly*, 30 F.3d 1144, 1153-54 (9th Cir. 1994), *cert. denied*, 115 S. Ct. 946 (1995); *United States v. Martinez*, 3 F.3d 1191, 1198 (8th Cir. 1993), *cert. denied*, 510 U.S. 1062 (1994). Beyond the threshold fact that petitioners chose not to present a Rule 702 question in their petition for certiorari, there is nothing in this case or in the briefing on petitioners' side that would call for reconsideration of the arguments that this Court rejected four years ago in *Daubert*.

CONCLUSION

For all the reasons stated, the judgment of the court of appeals should be affirmed.

Respectfully submitted.

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July 29, 1997

TABLE OF CONTENTS

SUPPLEMENTAL APPENDIX ("S.A.") TO BRIEF FOR RESPONDENTS

Item **Page**

DEPOSITION OF DANIEL T. TEITELBAUM, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

Deposition of DANIEL T. TEITELBAUM, taken on behalf of Defendant General Electric Company, pursuant to Notice of Taking Deposition in the above-entitled action, on Tuesday, October 12, 1993, at 10 a.m., at 3306 Independent Square, Jacksonville, Florida, before Shelli Kozachenko, CSR, RPR, and a Notary Public in and for the State of Florida at Large.

* * * *

[4]

DANIEL T. TEITELBAUM,

having been produced and first duly sworn as a witness, testified as follows:

Q Would you state your full name, please?

A Yes. It's Daniel T. Teitelbaum, T-e-i-t-e-l-b-a-u-m.

Q Dr. Teitelbaum, I see that you have brought with you today a number of items. Would you identify those for the court reporter, please?

A Yes, I will. This is my correspondence file which has correspondence between Mr. Warshauer, other members of his firm, and my office. This blue folder is [5] series of summaries of Mr. Joiner's deposition, Dr. Schecter's deposition, and a case summary prepared in my office of Mr. Joiner's medical records.

Let's make it orderly if we can. This is my chart of my medical examination and history of Mr. Joiner. The yellow

binders, bright yellow binders, are, one, a bibliography and the original papers dealing with lung cancer in animals and humans and PCBs with just a bibliography separate, so in case you don't want to mark the whole thing, you've got the separate bibliography; two copies of the Hazardous Substances Data bank on PCBs dated October 1993, the most recent review being the 7th of August of 1993 under peer review committee; Dr. Schecter's deposition — I'm just going to put that on the floor; I suspect you don't have any particular desire to do anything with that — and Mr. Joiner's deposition, which is in the brown.

In the blue are the medical records of Mr. Joiner which were supplied to me by Mr. Warshauer's office. Do you want to — are you going to want to attach those?

MR. FREEMAN: May I see them?

THE WITNESS: (Tenders the document.)

And then three black binders which constitute the discovery information obtained by Mr. Warshauer's **[6]** firm which was sent to me in connection with the case; a single page which represents one of what I understand are many analyses of PCB-containing mineral oils in the various transformers, but this is just a single one, and it's reproduced also in the blue folder; and then the original complaint which was filed in the case.

Q And I notice you have some books there as well.

A Yes.

Q What is the red book?

A The red book is the second edition of the International Program on Chemical Safety, the World Health Organization Environmental Health Criterion on PCBs which was just released. It's a 1993 publication, the update of a previous — which I think was 1979, if I remember correctly. And this is the June 1989 ATSDR toxicological profile for PCBs.

MR. COCHRAN: All right. If we could, I want to mark all these as exhibits.

* * * *

[11]

Q Now, I think you indicated that you had in a yellow folder a bibliography?

A Yes. I have a bibliography entitled "Lung Cancer and PCBs."

Q All right. What you have here is first you have a bibliography, then you have a bibliography with abstracts —

A Right.

Q — and then you actually have —

A The articles.

Q — the articles themselves.

A Correct.

MR. COCHRAN: Okay. Why don't we mark these as 12A, B, and C.

(The instruments were marked for **[12]** identification as Defendant's Exhibits 12A, 12B, and 12C.)

Q Have the bibliography, the bibliography with abstracts, and the actual articles themselves now been identified as Exhibits 12A, B, and C?

A Yes.

Q And who compiled the bibliography?

A I compiled the bibliography. My librarian actually put it in the technically correct form.

* * * *

[19]

Q Dr. Teitelbaum, do you have in front of you your handwritten notes from when you met with Mr. Joiner?

A Yes, I have my notes and my summaries of the deposition, and I will shortly answer your question.

Q All right. When did you make these handwritten notes, by the way? On what date?

A As I was sitting and discussing them with him, and I saw him on 7/14/93.

Q Where did you see him?

A In Atlanta.

Q Where in Atlanta?

A In a physician's office, and I'm sorry, I don't remember the doctor's name. **[20]**

Q How long did you meet with Mr. Joiner?
A About two hours, perhaps two and a half.

* * * *

Q What was the purpose for you making these handwritten notes when you interviewed him?

A It's a history. When I take a history from a patient, I begin at the beginning of the story and try to write as complete a story as the patient chooses to tell me, and then I ask him specific questions. And eventually I hope I have a complete picture of what the patient did, what's wrong with the patient, what the patient's present and past complaints were, something about family history, and so on. It's a fairly traditional medical exercise.

* * * *

[21] Q When you met with Mr. Joiner on July the 14th of 1993, did you conduct a physical examination of him?

A Yes.

Q What did you do?

A There's a notation of physical examination. I did as complete an examination as one could do not [22] working in one's own office, but actually there was pretty much everything that I needed, and so I did a typical examination just as — about the same as what I would have done had I had him in my own office, took his vital signs and went through and looked at him. I did not do any laboratory work, but I did enough of an examination to know what his condition was at the time that I saw him.

Q All right. You say you didn't do any laboratory work. Did you order any blood tests?

A No.

Q Any other diagnostic tests?

A No. He's had a very large amount of laboratory work, most of it quite recently. There was no reason to do that.

* * * *

Q All right. Now, let's see. What else do we have there?
A Just these two — the ATSDR document and the WHO

criterion document.

[23]

Q All right. If you would, identify on the record what they are.

A Yes. The first is the Environmental Health Criterion Number 140 entitled Polychlorinated Biphenyls and Terphenyls, Second Edition, World Health Organization, Geneva, 1993. It carries ISBN Number 94-4-157-140-3, and you can get it from WHO for 70 Swiss francs. I think they have a publications office in Albany, New York.

And then the second is the Toxicological Profile for Selected PCBs, published by the Agency for Toxic Substances and Disease Registry in June of 1989, and you can get this from the U.S. Department of Commerce, National Technical Information Service, Springfield, Virginia 22161. Carries the document number PB89225403.

Q Are there any other documents that you have reviewed which we have not identified this morning for purposes of this case?

A No, I read every month. We do a current awareness survey on PCBs, and so I have volumes of articles on PCBs that I've collected and read over the years, but I don't think they're particularly relevant [24] to this morning's discussion.

* * * *

[26]

Q Now, I noticed at the beginning of Dr. Schecter's deposition, you had sent a medical evaluation to his office on the evening or afternoon before his testimony.

A I didn't send anything to him. Mr. Warshauer may have sent a copy of the chart to him. I have never discussed this case with Dr. Schecter, never had any correspondence with him, and never sent him anything.

* * * *

[28]

Q All right. If you would, Dr. Teitelbaum, would you simply tell us what opinions you have reached in this case?

A Yes. I would say I have three opinions. The first opinion is that to the best of anyone' diagnostic capacity, Mr. Joiner had lung cancer and has been treated and is currently in remission from that lung cancer.

Secondly, it's clear that for a period of many years, Mr. Joiner worked as an industrial electrician and had exposure to various materials commonly used in that trade, including mineral oils contaminated with PCBs.

And, there, that his lung cancer was caused by or contributed to in a significant degree by the materials with which he worked.

* * * *

[31]

Q Do you know from any source what concentrations of PCBs were contained in any of the transformers on which he worked?

A I don't have those documents. I understand there are such documents; I have not seen them. Typically, in my experience, transformers which were listed as non-PCB transformers throughout this last 20 [32] years had concentrations from anywhere above 50 parts per million to something under 1 percent, maybe 5,000 to 8,000 parts per million at the maximum.

Q And is that something you're assuming for purposes of your opinion?

A Well, it's fairly typical of the era. I think it's reasonable to assume that that's so, yes.

Q All right. Do you know how long Mr. Joiner was exposed to mineral oil contaminated with PCBs, how many years?

A Well, he began work in 1973, and he says he thinks he stopped sometime around 1987.

Q So you would be assuming a 14-year exposure?

A That's what he believes he was exposed — that's the period that he says. He says he does not know what the situation was after that.

Q In reaching your opinion, though, what length of time are you assuming?

A Well, that's the assumption that I have, because I have no history of his having worked with these materials before 1973. His medical history prior to that indicates that he worked — did a little farming, some farm chores early, and worked as a

delivery boy and stocker — let me get the exact — baled hay and picked watermelon while he was in high [33] school up to 1972, and then in 1973 he began to work for the public utility.

Q Now, during the years that Mr. Joiner may have been exposed to mineral oil contaminated with PCBs, how often, if you know, was he exposed?

A I don't have, and have not seen that anyone has collected, the transformer records for who worked on them. I don't know how this utility works as far as its record maintenance is concerned, but other utilities that I've looked at keep a log for every transformer, and actually one could set up a record of how many he worked on, but how many hours it took him to do each job, it would be difficult to say. But from his descriptions to me, it was a very frequent activity.

(Mr. Freeman leaves room.)

Q On the order of daily?

A I would say several times a week, not necessarily daily. It's more likely that there were periods that were quite intensive and went on for a number of days when he was working on a large transformer and baking it out, something of that sort, than that it was every day. So I think it was episodic but not every day.

Q Have you seen any documents that would reflect the presence of dibenzofurans, dibenzodioxins, [34] or chlorinated benzene in any of the mineral oil on which Mr. Joiner worked on or around?

A I don't have any documents which would answer that question. There are, so far as I can tell, no quantitative analyses that have been supplied to me that answer how much and when.

(Mr. Freeman enters room.)

Q Or if any; is that correct?

A I don't have any documents at all. I think that one simply has to look at the likely chemistry of the situation and what's known about PCBs manufactured in this period and assume that there was some furan present, that there may have been some dioxin present, depending on the particular fire and circumstance. There probably was some chlorinated benzene since that's almost always a contaminant.

Q But that's speculation on your part in this case, is it not?

A No, it's not speculation. It's a reasonable assumption based upon what we know about the era.

* * * *

[44]

Q I want to make sure I've covered your second opinion. Have you, as far as you know, given us all of the facts on which you base that second opinion, that Mr. Joiner for many years had exposure to various mineral oils contaminated with PCBs?

Q Well, I haven't talked at all about how he worked and the conditions under which he worked, all of which contributed to that.

Q All right. Tell me what facts you rely upon there.

A Well, for the first, at least, 12 to 13 years of his work he had no protective gear. He worked with [45] and in the oil on a regular basis. He describes frequently having his skin doused with oil. He describes needing a new pair of shoes every six months because of the oil destroying his shoes. He describes being inside the larger transformers on many occasions and being covered with oil. He describes inhaling the smoke on a number of occasions from baking out transformers.

He describes his desk as being in the area where the transformers were actually being serviced, so that — and his tools being constantly covered with oil. Again, this is very typical. Every electrician that I've ever talked to from this era told me that they used to use the oil from the transformers to oil their tools to prevent rust and to keep them in good shape. So he has multiple exposures by dermal and respiratory route.

* * * *

Q All right. Now, let's turn to the third opinion which was that — and I'm paraphrasing, so if [47] you want to go back — if I misphrase this, feel free to correct me, but as I understood it, your opinion is something like the lung cancer was caused by or contributed to in a significant degree by the materials with which he worked.

A Good notes.

Q All right. Now, tell me the facts on which you relied in reaching that opinion.

A Well, it's my opinion that cancer is a multifactorial disease. As a consequence of this multifactorial pattern of causation, various individuals respond with malignant disease at some time in their lives, and it is unusual for a single cause to be identifiable.

In my analysis of the information available concerning Mr. Joiner, I find three interesting factors. The first interesting factor is that there is at least one case of lung cancer in a first-order relative. There is not much evidence that sporadic cases of lung cancer have a familial pattern. There are recently some interesting studies on families of lung cancers, but they're pretty unusual. But there is at least one case in a smoker in his family. That's the first interesting thing.

The second interesting thing is that we do [48] know that Mr. Joiner smoked for a relatively significant period of his life, but from the point of view of causation of lung cancer, a very — a low-end dose and early, and he stopped 12 years approximately before he got sick. But if the most recent studies on smoking and cancer are correct, our previous assumptions that as time passed the risk would disappear may have been unduly optimistic. So we have some risk of lung cancer because he was a smoker; however, the likelihood of his developing lung cancer at age 37 on a statistical basis is extremely small.

If you compare the lung cancer rates at age 60, which are around 400 per 100,000 person years, with the lung cancer rates in the 30s, which are almost too low to detect, somewhere around 10 to 15 per 100,000 and most of those in the later 30s rather than the early 30s, it's pretty — pretty low risk, but it's there.

The third thing is that we have a period of approximately 15 years of exposure to a material which, in and of itself, is an animal carcinogen, likely contaminated with additional materials which are animal carcinogens, carried in a vehicle which is a known carcinogen, and other work which he did which had some potential carcinogen exposure. It's not quite so clear, but he talks about using mineral oil as a — using [49] mineral spirits as a cleaning solvent.

So I see his occupational exposure to the materials containing — to mineral oil containing PCBs as a significant portion of his history. I am a firm believer in the concept that if there is more carcinogen exposure, there is more risk of cancer and more cancer

in fact, and I believe that in that fashion, at least these three issues, some perhaps genetic predisposition, not well characterized, about which we know very little; smoking, about which we know more; and an occupational carcinogenic exposure to a material known to be an animal carcinogen and quite strongly suspected by most people being a human carcinogen as well, I think that those elements together are a significant portion of the causation of this disease.

Q Now, which of these substances is the known animal carcinogen?

A Well, I think that there's very little question that PCB is. There's sufficient information on PCBs. I brought the IPCS World Health Organization criterion because it's just hot off the press, and the summary which appears on page — let me find it — 478 indicates that as of 1987, IARC had concluded that the evidence for carcinogenicity in laboratory animals is sufficient. This is the latest piece of information, **[50]** and there is no reason to doubt that, and they also concluded that PCBs are probably carcinogenic for humans.

Q Is it your opinion that Mr. Joiner's lung cancer was initiated by his cigarette smoking?

A I don't have an opinion about that. That would be purely speculative. It could have been. It could have been initiated by something entirely other than that. I think what's clear is that when you stop smoking, the promotional effect goes away, at least the nongenotoxic promotional effect.

Q The promotional effect of what?

A Of the cigarette smoking.

Q Is cigarette smoking a complete carcinogen?

A Hard to answer the question. I think there are components in cigarette smoke that have the potential for being complete carcinogens. For example, ethylene oxide is present. I think ethylene oxide can be both a promoter and an initiator. On the other hand, there are — and there are anthracenes and various polynuclear aromatics, all of which appear to have the capacity to be complete carcinogens.

On the other hand, there are a lot of materials which are only initiators, like urethane which is in cigarette smoke, or the tars which are probably **[51]** purely promoters. If you go back to the earliest research in cancer, the Rouses' work on chicken papilloma,

the promoter used in those tar, coal tar in that case but not terribly different from cigarette tar.

* * * *

[61]

Q All right. In addition to mineral spirits, cigarette smoke, and PCBs, were there any other chemicals in Mr. Joiner's workplace that contribute to your opinion?

A In the occupational/environmental history which I took from him, he listed oil and paints as the only other two materials, the oil being something apparently other than the PCB oil, and the paints being apparently an occasional exposure. And I would think that the paints, if they're a problem, are a problem because they contain mineral spirits in some instances. That's all he indicated he worked with, so that's all I would point to. I don't have anything else.

* * * *

[65]

Q All right. You've identified oil, you've identified paint, you've identified mineral spirits, you've identified PCBs. Is there any other chemical that was present in Mr. Joiner's workplace that you believe contributed to his lung cancer?

A Not according to anything he told me. I don't know of any other chemicals that were present, period. That's all we have.

* * * *

[70]

A Can you say to a reasonable degree of medical probability whether Mr. Joiner's body burden of PCBs was higher than background nonoccupational levels before his diagnosis in August of '91?

A I have no opinion about that. It would be pure speculation.

Q Why would it be pure speculation?

A Because you don't have a measurement from before; you don't have any way of comparing it to the general population; you don't have anything that you could base that on. It would be absolutely a guess.

[73]

A In my opinion, exposure is all that can be calculated in this, and that would be a very rough calculation which an industrial hygienist might do, taking a very careful history of, let's say, a series of incidents and then setting up a model for how much of this PCB would have been on the skin of the individual, how much PCB and mineral oil would have been in the air, depending on the temperature and so on, and then you come up with a total exposure assessment. That would be different from the dose.

Q You haven't done any sort of modeling in this case, have you?

A Well, I don't have enough data to do that. Obviously I'd have to start out by knowing what's in the material, and that hasn't been provided to me if it exists.

Q So you don't have any quantitative data to assess either exposure or dose here.

A That's correct. I would not have any way to do it. I don't have any reliable measure of PCBs in his body before he became ill. I don't have any reliable information concerning the contamination. I only know that in the era we are talking about, the typical [74] materials were contaminated, as I've previously discussed, and he worked with it over a long period of time, and material is absorbed through the skin. That's as far as we can go.

And that's typical of what we know in retrospect in industrial hygiene or occupational medicine studies. The person who is ill can rarely give you anything more than that.

Now, when we come back to this table 20 years from now, both of us grayer and older, perhaps we'll be able to look at numbers which have been collected since 1985 which will tell us enough so that we can, in fact, model the exposure.

* * * *

[81]

A . . . The concept of cancer or carcinogenesis as a biological problem is discussed in at least two — I think two good books. One is Hathway's book on chemical carcinogenesis, and the other is Berenblum's book, that's entitled Carcinogens as a Biological Problem. There are lots and lots of papers, Farber's papers and Smuckler's papers and many others, in which the attempt to understand the strategy of carcinogenesis is laid out.

I think that it is a multifactorial disease.

* * * *

[83]

A . . . A promoter by definition is never a complete carcinogen. It may, in fact — a complete carcinogen may have both initiating and promoting qualities, but you can expose someone to a promoter forever; if they don't have an initiator, they will never get cancer. So it's necessary, but not sufficient.

* * * *

[84]

Q Well, if a chemical as a general matter is characterized as a promoter of cancer in humans, do you [85] classify it as a human carcinogen?

A It might be, but it is a chemical which participates in the generation of cancer. See, this is really a — it's a failure of the current terminology because our regulatory system and the scientific knowledge are not necessarily concordant. You surely don't want to go around exposing people to promoters.

Q Is that because they have a — as a general matter they would have a carcinogenic potential?

A No, it's because they would cause more cancer, but not because in and of themselves they're carcinogenic. And I think we're playing with words here. I think it's like saying if you need a detonator and dynamite together to get an explosion, is the detonator considered an explosive? And it may be for the Alcohol, Tobacco, and Firearms Division, and you maybe would get charged with possession of explosives if all you had was the detonator in your hand, but that isn't going to blow up.

Q Well, let me ask you this: When we distinguish between the term carcinogenic and the process of carcinogenesis, you would include a promoter within that process.

A It's part of the process. I think that that is clear. I think that if you read Berenblum's book [86] which presents — unfortunately, since he's passed away no one's gone back and redone it; it's a mid 1970s analysis. He takes every theory of carcinogenesis which had been proposed as of that time and critiques it logically. It's a brilliant piece of work on cancer, and he lays out all those issues.

Or you read I. B. Weinstein's papers on co-carcinogenesis. And I think that our concept of complete carcinogens is very limiting, probably only relates to ionizing radiation in and of itself and some alkylating agents like ethylene oxide and one or two others where it's clear that it both initiates and promotes.

For most substances you have a mix, and you have to have the substances together to produce cancer. The way we define it in a regulatory sense, or the way IARC defines it, is if you have more of this, then you get more cancers in animals and people, and it really doesn't matter what the fundamental mechanism is, is it an initiator, a promoter, a complete carcinogen, a co-carcinogen, a modifier, a penetration enhancer, or any of a lot of things.

Q All right. Is consistency a principle of toxicology?

A Consistency is a principle in science. In **[87]** theory you should be able to do an experiment a certain number of times and get an outcome more often than due to chance.

Q All right. Let me ask you this: Based on the animal studies that you're aware of, has there been a consistent causation by means of promoting of lung cancer in two different animal species?

A That sounds like a regulatory definition, and I just don't think I'm going to be able to answer that. I think that's got words in it I don't understand.

Q Which words don't you understand?

A Well, I know what consistent means scientifically, but I don't know what consistent means in that sentence. Are we talking that if you did a hundred studies, it would be more often positive than you would expect due to chance? Is that what your definition is?

Q Other than the studies by Lucy Anderson, do you know of any other animal study where lung cancer was promoted in a species other than mice?

A I don't think anybody's studied any other study. I think that now that the 1993 Anderson publication came out, I suspect you're going to see some more studies on that because now there seems to be a clean model that can be looked at. **[88]**

Q Is biologic plausibility a fundamental principle of toxicology?

A Yes.

Q All right.

A Well, no, wait. It's not a fundamental principle of toxicology, it's a fundamental principle of epidemiology, and it comes from Bradford Hill's criteria, and it is a fundamental principle which attempts to assess inference of causality based on scientific study.

Q Is it sufficient to establish biological plausibility to find carcinogenesis in only one animal species?

A It's a pretty good start. I mean, I think it is —

Q Is it sufficient?

A I think it's sufficient when you have all of the other information you have about PCBs as carcinogens. It's perhaps not sufficient to establish that a particular kind of cancer would occur in all animal species, but it certainly is much more consistent with the total body [sic] than if she had not found it.

If you came to me and you said, "Dr. Anderson had done this study and it's negative. Is that consistent?" I would say, "No, that's not consistent. **[89]** That's perhaps revolutionary." In fact, I would think that if you studied any kind of cancer well, you would find that it's probably — that PCBs are probably capable of promoting that cancer in a particular study design.

MR. COCHRAN: All right. Would you read that answer back to me, please, ma'am?

(The preceding answer was read by the reporter.)

THE WITNESS: Body of knowledge, I think, is what I said.

THE REPORTER: Oh, I'm sorry.

BY MR. COCHRAN:

Q Now, turning to your bibliography, I think we identified as Exhibit — is it 12A?

A Yes, right.

Q All right. What, if any, epidemiological studies have you reviewed in reaching your opinion?

A Well, I think I've reviewed all of those that are around on PCBs. I think that the study which in the long run will give us the most information is probably Bertazzi's group. I just saw Professor Bertazzi in Nice and I asked him if he has anything new coming out, and he says yes, he has something new coming out, but he wouldn't tell me what it was, so I don't know what it **[90]** is. Apparently, they've done some further study of this group of capacitor workers.

He could have another five years of observation, which would be a lot of person years. I think that's the best study. You've got Kuratsane's studies from Japan. You've got a few cases of lung cancer there. They're not very convincing, as the Japanese lifestyle is different. There's — it's, again, suggestive but not convincing.

I think that the recent review by IARC of all of the studies, including Gustavsson, who was also at the meeting, and Hogstedt, who was also there, and — all of whom talked about this, I think everybody is willing now to take the position that PCBs are human carcinogens, but I don't think that they would — any of them would be willing to say that they have evidence, convincing evidence, that PCBs cause any single kind of cancer.

I think they would say that they are human carcinogens and that the evidence now is that they can promote a whole series of cancers: hematologic, kidney cancer, certainly lung cancer is on the list. They've been observed and they appear to be out — by Bertazzi's work, well out of proportion to what would be expected.

Q Okay. You said you have reviewed all of the [91] epidemiologic studies. Are there others that you have reviewed that are not on that list?

A These primarily were the ones that dealt with — that mentioned lung cancer and so on. Yes, there's a whole series of them listed in that WHO document, and I've — whenever one comes out, I collect it and I read it.

Q Do all of the epidemiological studies show the same thing; that is, are they consistent?

A No, but — all do not, but there is certainly general agreement that for groups which have been studied long enough and for which the exposure is well enough characterized, there is an increased risk of cancer in humans. But you have a vary varied group. You have groups where you have mostly women exposed; you have groups where you have mostly men.

Most of the studies come from capacitor workers, not from people who did this kind of — the work that Mr. Joiner has done. I don't know of a study in industrial electricians. Be interesting to do, but I don't know of such a study. And probably it would be one you could do because a lot of these people belong to the unions and would be fairly easy to identify.

Q Did the Bertazzi study have a very short follow-up period?

[92]

A Yes, that's why I said he — he published it in '87, and I think he wrote it about — sometime in '86. We could theoretically have another five or seven years of follow-up, but he says he has something in the works, but wouldn't tell me anything about it.

Q If an epidemiological[] study has a short follow-up period, does that put a limitation on the interpretation of the results?

A Can put a lot of limitations. If you're dealing with something which is very highly penetrant, a disease which occurs quickly and very often, like if you study leukemia in radiation victims, and you've got five years of follow-up, it's clear in five years that you're going to have an increase in leukemia in people exposed to radiation.

On the other hand, where you're dealing with something which is a relatively weak carcinogen and a relatively rare disease — I mean, if you wanted to study PCBs in electricians at age 35, I haven't done the calculations, but you'd need millions, I think, millions of exposed people to get a statistically significant finding, or millions of person years anyway.

Q What was the size of the cohort that Dr. Bertazzi studied?

A I think 1500 approximately. .... [93]

Q So would that, again, having a small cohort, be a limitation on his results?

A Got to wait longer.

A Well, you need a number of person years of exposure and a number of person years of follow-up. You can get the number of person years of follow-up by having a big group for a short time or a small group for a long period of time. A thousand person years of follow-up standardized over, they may give you an answer comparing studies, but —

Q Then would the study be inconclusive due to low statistical power?

A That's one of the accusations that have been made, and he himself says that they — you know, that the lung cancer occurrence was tending or trending towards statistically significant, but was not statistically significant.

That doesn't really mean anything, as you well know, because statistical significance is not the only criterion for interpreting

information. It suggests [94] that there may be an error in the study, but if it's biologically plausible and it's consistent with other studies, even though it doesn't reach statistical significance, you'd best be very, very cautious in saying the effect isn't there.

* * * *

[95]

Q All right. Let me ask you: Based upon the epidemiologic studies that you've seen, is there a finding of a significantly increased incidence of cancers of a general type in an exposed population when compared to an unexposed population in a carefully documented epidemiologic study?

A I think that's a subject for a doctoral paper, [96] and I'm going to say it's too vague for me to answer. You're going to have to tell me what you mean. Are we talking about all cancers? Are we talking about general populations? I think that the question you're asking me now has been answered by the expert committee that IARC had together, and their conclusion was there's enough evidence to say that it's probably a human carcinogen, there is not enough evidence to say that is proved, and I think I would have no problem accepting that.

Q And when you say that it's a human carcinogen, you're just talking about generally without respect to any particular —

A That it's capable of causing cancer in humans, without saying which cancers it's capable of causing. I do not believe that there's any good evidence that PCBs in any specie have a signal lesion. I mean, we have a whole series of cancers which have been observed as increased: kidney cancer, lung cancer, hematopoietic cancers. I've even seen one study on prostate cancer. Lots of opportunities.

Q Are there criteria which you as a toxicologist should meet to reach a conclusion to a reasonable degree of medical probability?

A About what?

Q Causation. [97]

A There's a nice discussion — there's a new little paperback epidemiology text by Greenburg and a group of colleagues in which he talks about the difference between probable as used by clinicians and probable as used by epidemiologists, and he points out that probable as used by clinicians is what most of the

world runs on. That is to say you look at all the information and you come to a conclusion that all the evidence together gives you the reasonable likelihood that your conclusion clinically is correct.

I think that as a toxicologist when I look at a study, I am going to require that that study meet the general criteria for methodology and statistical analysis, but that when all of that data is collected and you ask me as a patient, "Doctor, have I got a risk of getting cancer from this?" That those studies don't answer the question, that I have to put them all together in my mind and look at them in relation to everything I know about the substance and everything I know about the exposure and come to a conclusion.

I think when I say, "To a reasonable medical probability as a medical toxicologist, this substance was a contributing cause," this substance being the contaminated oil was a contributing cause to his cancer, that that is a valid conclusion based on the totality of — [98] the evidence presented to me. And I think that that is an appropriate thing for a toxicologist to do, and it has been the basis of diagnosis for several hundred years, anyway.

MR. COCHRAN: Let's take just a short break, if we could, Michael.

MR. WARSHAUER: Okay.

(Short break.)

BY MR. COCHRAN:

Q Did you recommend that Mr. Joiner undergo any other diagnostic tests, x-rays, CAT scans, anything else like that?

A Oh, heavens, not at this time. I certainly wouldn't expose him to any more radiation. He's had enough radiation at this point. If he needs therapeutic radiation, you don't want to use up his potential exposure on unnecessary tests.

* * * *

[106]

Q So how often do you testify?

A By deposition?

Q Or court appearance or at a hearing.

A In court, not more than three or four times a year, maybe five times a year maximum, some years not at all. I think in '90 — was it '91 or '90, there wasn't a single court appearance. By deposition, perhaps three or four times a month.

* * * *

[110]

Q Now, to be specific to this case, is there any study that you know of anywhere in humans that indicate that small-cell, being specific to this diagnosis, lung cancer was caused by PCBs?

A No. It's an impossible research question to investigate, I think, in the first place, and in the second place, there is no such study.

Q I see.

A So I think it's — in other words, I think that you couldn't do the study, and I don't think one exists at the present time. [111]

Q I see. The same question with respect to PCBs as contributing to small-cell lung cancer in humans.

A That, I think could be done, but has not been done.

* * * *

Q Now, can you point to any study in animals where the person conducting the study has suggested that the animal developed small-cell lung cancer?

A I don't think there's an analogy in animals that would be relevant, so I can't point to such a study. [112]

Q Okay, sir.

A We've talked about the Anderson studies. I've given you the bibliography which I consider to be relevant. I do not believe that there is an animal cell type which is sufficiently similar to say that you could conclude A was the same as B. It's rather different from, say, osteogenic sarcomas where you have a better comparison, but perhaps more like the lymphoma/leukemia problem where animals seem to develop analogous lymphomas but not analogous leukemias.

Q Dr. Teitelbaum, I'm going to ask you a few questions, and I won't move if Michael will back up a little bit and you can hear me.

As I understand it, you work for a corporation?

A I have what's called a professional corporation. You can call it that.

Q What is the name of your corporation?

A Daniel T. Teitelbaum, M.D., Inc.

Q And you own 100 percent of the stock in the corporation?

A Yes, that's correct.

* * * *

[114]

Q — what do the other 14 employees do?

A Well, I have four people who work in my clinical are and do typical nursing, and I have an x-ray tech and a laboratory person and so on. I have two full-time library sciences people and at least one assistant in addition. I have —

Q What do they do, library science?

A Well, you see, you've got a bibliography here which is carefully put together. We have more than 40,000 articles catalogued, all of which have been read and assembled, and they're all accessible through computer databases and so on.

Q They keep up with the literature and —

A I keep up with the literature, and they do what I need technically in order to have the literature in front of me, to have it assembled and so on. We have — we're part of the National Library of medicine system, and we actually have the beset toxicology collection in the area. People borrow from us rather than the other way around. We get 46 journals in toxicology.

* * * *

[116]

Q Now, you said you took the examination of — [117] the medical examination and history of Mr. Joiner in Atlanta?

A Right.

Q And who attended that history with you?

A Just his wife and us.

Q Okay. The three of you in the room the entire time, or did she leave the room?

A No, she stayed the whole time.

Q And no one from the attorney's office?

A Mr. Terry — I'm sorry, I don't remember his name — came with us, but no —

Q Did not stay in for the examination?

A No.

* * * *

[118]

Q Now, you referred to this book and I think specifically this book is called The International program on Chemical Safety, Environmental Health Criterion 140, PCBs, Second Edition.

A Right.

Q And you referred, I believe, to page 478.

A Right, the summary page.

Q 477, which is paragraph — all right, 478 which is the first — let me see if I can find this. First paragraph, which says that PCBs were evaluated by IARC in 1977 and 1987. In 1987 the IARC concluded that because the role of impurities in PCBs and the carcinogenicity could not be excluded and because of the lack of knowledge on dose response relationships, the evidence from epidemiological studies is limited. However, the evidence of carcinogenicity in laboratory animals is sufficient, taking the combined evidence from human experimental animal studies, the IARC group concluded that PCBs are probably carcinogenic for humans.

A Right.

Q And you agree with that statement?

A Yes, I do.

EXHIBIT 12-A TO TEITELBAUM DEPOSITION

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DEPOSITION OF ARNOLD J. SCHECTER, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

Deposition of ARNOLD J. SCHECTER, M.D., held at the Bache Building, Binghamton, New York, on the 14th day of July, 1993, commencing at 9:15 AM.

* * * *

[4]
ARNOLD J. SCHECTER, M.D., having been called as a witness, being duly sworn, testified as follows:

* * * *

Q Were you served with a subpoena, a copy of which I've marked, it's the second two pages, as Schecter Exhibit 1?

A Yes, sir.

Q Let's turn to the third page of the exhibit which is attachment A.

A (Witness complies)

Q With respect to the first numbered item, "Any and all published articles evidencing any and all research conducted by or participated in by you concerning PCBs, dioxins, dibenzofurans." All such [5] articles, were those made available to me yesterday in your library?

A You had full access to my office and library yesterday, yes, sir, when you were present in my office.

Q Am I correct that after we conclude today, if we have time, I can go back and take a further look at those materials?

A Of course.

* * * *

[6]

Q Looking at the records I'm going to hand you, were these the medical records that were produced yesterday, is that all of them that you've seen that were produced yesterday?

A No. I believe that in addition to this, there was one other fact that came at the end of the day.

Q What was that?

A That was a medical evaluation from Dr. Teitelbaum.

Q Have you reviewed that?

A No, I have not. [7]

Q Did it form any basis of your opinion?

A No, sir, it did not.

Q Did you read it?

A No, I did not.

* * * *

[16]

Q Have you seen or reviewed any photographs or video-tapes concerning this case? [17]

A Yes, I have.

Q What have you seen?

A I saw a videotape of the work area where Mr. Joiner worked and I believe still works.

Q When did you see this videotape?

A I saw that in the last few months in Mr. Warshauer's office in Atlanta, Georgia.

* * * *

Q Tell me what you do recall about the videotape.

A I recall seeing a work area that was underground, was rather small, no particular separation of toxic chemicals from desk work areas. No worker safety gear or no evidence of separation between the areas where toxic chemicals would be present from transformers and ordinary desk eating, smoking or work areas.

* * * *

[19]

Q Have you ever been to Thomasville, Georgia?

A No, I have not. I would add one comment on medical records. I assume you are speaking of traditional medical records. There are, of course, also adipose tissue chemical levels that were done on this patient.

Q But you don't have those records in your files, do you?

A To the best of my knowledge, I do not.

Q Have you ever been allowed to review those records?

A Yes, I have.

* * * *

[24]

Q In your standard practice, isn't it routine and customary for you to have blood tests run so that you can get a congener — congener specific level determined for dioxins, furans and PCBs?

A No, it is not.

Q To your knowledge, has another blood test for Mr. Joiner to determine dioxin levels actually [25] been done?

A Not that I know of.

Q Do you know why?

A I'd be happy to share with you my evaluations as to the usefulness of doing it, if that's what you are asking me or would like to know about it.

Q The question is: Do you have any knowledge as to why it was not done?

A Well, I suggested — I did not suggest. I informed Mr. Warshauer and his colleagues that we do not know how to interpret blood or adipose tissue dioxin, dibenzofuran or PCB analytic data after cancer and cancer chemotherapy and radiation treatment of cancer. Particularly with weight loss and then weight gain, there is no published research that I'm aware of, and this is a field in which I work full time, concerning how best to interpret or how to interpret meaningfully such data. So, to order a test when you don't know how to interpret it is not usually something I do in my practice of medicine. And it's an expensive test. It's a $2,000 test usually for a day in a dibenzofuran analysis. It's not one to be entered upon trivially [26] and certainly not if you don't think it's going to be useful within the practice of medicine.

It would be an interesting research project which I have proposed, as you may or may not know, that we look into how to interpret these tests in cancer patients.

* * * *

[28]

Q What scientific research or articles in your methodology of analyzing this, what scientific articles or other empirical data are you relying on for this conclusion, for this opinion? Can you name an article for me?

A Well, as I mentioned to you previously in my own published article on dioxin levels in AIDS patients, we found that in a cross-sectional study which has been published, pooled blood from sick AIDS patients had an elevated level of dioxins as compared with HIV infected and that is the virus that causes AIDS infected patients who were not sick or asymptomatic. And also, the levels in the sick AIDS patients were elevated as compared with the general population without the virus. The interpretations included what appeared to us to be quite logical and that was that the treatment may [29] have affected the levels of these chemicals.

Q It may have, you just don't know?

A It may.

Q You don't know?

A Let's follow logically. If your colleague who weighs considerably more than you and has more adipose tissue, probably has 30 percent adipose tissue as compared to your 20 percent, if he were to lose — let's say he had this — a special exposure to dioxins[,] dibenzofurans or PCBs and had an arbitrary value of 100. If he loses half of his adipose tissue, then half of those chemicals in his body would be gone. If he then regained his weight, the new adipose tissue would not necessarily reflect. It would reflect the dilution because he would only have a portion of the chemicals to which he was previously exposed. I think that's straightforward logic and whether that's in a published article or not, I don't know.

* * * *

[32]

Q Where did you meet Mr. and Mrs. Joiner?

A [33] In Mr. Warshauer's office in Atlanta, Georgia.

Q Why did you meet them?

A I wanted to talk to them to get a feel for Mr. Joiner, to be able to have him describe to me what his exposure was in general, what his occupations had been like, what his chemical exposures might have been, what his medical history may have been to get a feel for what kind of person he was, whether he was a person I would find believable or not believable, to evaluate him and his cancer and to try to come to some conclusion as to the causation of his lung cancer.

Q Was there any other reason for you to meet him?

A Not that I can think of at this time.

Q Now, you are an MD, is that correct?

A Yes, sir.

Q Did you physically examine Mr. Joiner?

A I don't remember — I certainly did not do a complete medical exam or complete physical exam. I don't remember whether I did anything specific such as look at skin, I don't recall taking a blood pressure. [34]

Q Did you take what some folks would refer to as your little black bag with you?

A I don't recall doing that. But I could have and I might not have. I just don't remember at this time.

Q Did you take his blood pressure?

A I don't remember.

Q Did you listen to his heart or lungs by means of stethoscope?

A I don't remember.

Q Did you take his temperature?

A No, I did not.

Q Did you order any tests for him?

A No, I did not.

Q Why not?

A Because he had a very thorough workup for his lung cancer and had been under intense medical care for a number of years when I saw him and I didn't want to put him through any more unnecessary hardship and I didn't feel the need for it.

* * * *

[40]

Q Now, what did Mr. Joiner tell you?

A He told me about his work history. He told me about his smoking history and about the diagnosis of his lung cancer. To a certain extent described his treatment and how he felt as far as having strength or not having strength, being tired all the time.

Q All right. He told you about his work history, he told you about his smoking history, he told you about the diagnosis, about the treatment and about how he felt.

A And a little bit about his family history, medical history.

Q And his family medical history. All right. Let's turn to the work history. Tell me everything you recollect he told you about his work history.

A Well, the major point I recall was that he started after high school about 1973 working in the job or for the firm he worked with, the government and the city and progressively moved up in seniority. That he handled electrical transformers and when he first handled them, including maintenance done on them by heating the [41] cores inside with hot lights, he did not have any knowledge that there may be — that there might be toxic chemicals involved. There was no warnings, he was given no instruction and he took no precautions with respect to person protective gear. And the cores of large transformers or smaller transformers were heated in some cases in the office below ground level where he worked. He also worked outside. He took courses to increase his knowledge and to move up progressively and he was still working, much to my surprise for the same company and in the same job.

* * * *

Q What else did he tell you about his work history?

A He told me that in a certain time in the 1980s he learned that PCBs were contaminates, PCBs were sometimes found or believed to be found or actually measured in some of the transformer oil [42] that he was working with and that somewhere in the 1980s personal protective gear started to be employed and I believe that consisted of full-face respirators and TYVEK protective gear.

* * * *

Q If you would, take a quick look at what we identified as Schecter Exhibit 6 and look at paragraph seven on page three.

A (Witness complies)

Q Did Mr. Joiner tell you that sometime at or about 1983, he would have learned about the contamination of the mineral oil, in some instances, with PCBs?

A I believe he said somewhere in the mid-'80s.

Q Is paragraph seven consistent with what he told you?

A Yes, it is.

* * * *

[46]

Q Did you review any of the medical records in Mr. Joiner's medical records where he had given his smoking history to his various treating physicians?

A Well, yes, I reviewed the material you and I looked at a few minutes ago.

Q Do you recall if what Mr. Joiner told you seemed to be consistent with his medical records?

A It seemed more or less consistent. As I understand from the deposition, there may have been a few areas where there was some disagreement as to when some doctors thought he had told them he had stopped smoking.

Q But in terms of what he had told you, did you think that what Mr. Joiner told you was consistent with the medical records? [47]

A It seemed to be.

* * * *

[49]

Q Setting aside the deposition for a moment, what do you recall he told you as an MD who was asking questions about his medical and smoking history? [50]

A I recall that he came from a family of smokers. He smoked many years. He gave up smoking. He had other chemical exposures and he came down with lung cancer. That's how I saw it as an MD. And he did not have asbestos or radon exposure.

* * * *

Q In terms of determining in your scientific methodology whether the chemotherapy may or may not have affected the level of PCBs, furans and dioxins in his adipose tissue, wouldn't it be

important to know what kind of chemotherapy was used?

A Well, as we mentioned earlier, there is no data at all on any type of alternations of dioxins, dibenzofurans or PCBs that I recall in published literature relating to specific [51] chemotherapy or radiation therapy or cancer therapy of any kind. The end result is thought to be — the end result of relevance is thought to be the weight loss or gain, although that may not be correct. Mr. Joiner and Mr. Warshauer told me or indicated that he had lost something like 30 pounds of weight and that he had subsequently gained or regained the weight, so there was — I had no reason to believe that I was not being told the correct information or truthful information. And so, there was a history of weight loss and then regain.

* * * *

[60]

Q Based on what you've learned in this case, what chemicals has Mr. Joiner been exposed to potentially?

A What stands out after the cigarette smoke is the PCB transformer fluids and the PCB, dioxin and dibenzofuran contamination. And when I say dioxin and dibenzofuran, I'm referring to chemical contaminants or breakdown products which are frequently found in PCB fluids or in transformer fluids. [61]

Q Any other chemicals that Mr. Joiner was exposed to?

A Not that I know of or that I can recall at this time.

Q Now, tell us what opinions you have reached in this case.

A I believe more likely than not that Mr. Joiner's lung cancer was causally linked to cigarette smoking and PCB exposure. And by PCB exposure, I'm thinking also of PCBs and dioxins and dibenzofurans and related chemicals which frequently are found together in transformer fluids.

Q Any other opinion?

A Well, that Mr. Joiner more likely than not has had a higher exposure or more exposure to transformer fluids and the chemicals in them than the average person, and this would include the PCBs, dioxins and dibenzofurans and related chemicals. And it seems to me from the history he's given, that until the mid-1980s, he was not aware of the fact that he was dealing with toxic chemicals and did not protect himself, nor did anyone attempt to protect him or inform him that he should be protected from these toxic chemicals. And this, of course, is a [62] breach of good occupational medicine or

industrial hygiene practice.

* * * *

Q Do you need any additional information in order for you to express these opinions?

A Not that I can think of at this time.

Q So, would these be considered your final opinions in this case?

A Well, if there is further information that would alter them, then they might not be final. I don't hesitate in coming to these conclusions at this time. They seem to be reasonable.

Q Do you plan any further investigation?

A I haven't really thought about that.

Q So, you've given no thought to any [63] additional investigation?

A Well, I would think that if this isn't settled in a reasonable fashion and goes to trial, then one might want to be a little more thorough with Mr. Joiner, although I think I've covered the major basis more than adequately. And —

Q You mean more thorough with his medical history?

A Well, I might want to do a somewhat more thorough medical evaluations, although at this time, I really do not see the need for it. And I might want to visit the site of his employment and look at the transformers, look at the room involved, but I might want to examine medical regards in more depth, although I don't see any point in examining the types of chemotherapeutic agents and their pharmacologic actions. I have sufficient knowledge for my purposes to know whether it would affect — know or not know as best anyone knows, how they might affect dioxin, dibenzofuran or PCB levels.

* * * *

[65]

Q Now, let's talk about your first opinion about the causal link. What facts do you base your opinion on that it's more likely than not that Robert Joiner's lung cancer is causally linked to cigarette smoking and exposure to PCBs and furans and dioxins, what facts is that opinion based on?

A Most lung cancer in the United States is caused by cigarette smoking. And with cigarette smoking in the presence of other carcinogens, for example, asbestos or radiation, the rate of lung cancer will go up markedly. PCBs, dioxins and dibenzofurans are definitely promoters of cancer, that is, once a cell has been initiated, once the cancer has been initiated in the cell, then these chemicals definitely will promote the cancer. In **[66]** addition, in animal experiments by themselves, dioxins, dibenzofurans and PCBs cause cancer in a dose-dependent fashion. We can probably leave it there unless you want me to elaborate.

Q Now, when you say that PCBs, dioxins and furans are definitely promoters, is that based on animal studies?

A That these cause cancer is animal and human study. That they are promoters is based on in vivo and in vitro studies. The in vivo studies in animals show that these chemicals alone or following dosing with initiators of cancer will cause increase in cancers. The toxicity is also studying for these chemicals by a number of biochemicals means such as enzyme induction. And recent work such as that of Dr. George Lucier and colleagues at the National Institute of Health have shown that humans — human tissue appears to be as responsible as animal tissue to these chemicals, as laboratory rats, for example, which are sensitive species. The human studies are studies such as the Yusho poisoning where an excess of cancer has been shown in some studies. And Dr. Fingerhut's NIOSH study, some Seveso studies where humans were exposed to dioxins as published by **[67]** Dr. Bertazzi and others, IARC studies, International Agency [for Research] on Cancer at the World Health Organization showing an increase in cancer in dioxin-exposed subjects and others.

Q I want to go back. When you used the term promoter, are you talking about strictly animal studies?

A These chemicals are considered a promoter based on evidence from laboratory studies.

Q On animals?

A On animals — primarily animal studies, yes.

Q Whose studies are you relying on?

A Many studies including that of Lucier and colleague. The studies I found, for example, many of them in the agency for toxic substances and disease registry toxicological profiles or PCBs and separate study or publication rather for dioxins and the separate

publication for dibenzofurans where they've attempted to catalog the majority of the studies which strongly show that these chemicals are very powerful promoters.

Q Again in animal studies, correct?

A The — well, by animal studies, are you **[68]** excluding humans as animals?

Q Yes.

A. You are refer to laboratory animals?

Q Yes.

A The studies for promoters per se have been primarily to date in animal studies. But human tissue has also been used for some studies of these chemicals and humans have been studied after exposure to the chemicals. But the difference is that we don't have the clear[ance] legally in this country to dose humans with toxic chemicals. The animal studies are far [more] powerful than the epidemiology studies where the sample size is smaller. We do not dose deliberately, so the dose is not known. The dose may be small. And latency periods cannot be followed as well as they can from animal studies or cell culture studies.

Q Again, your opinion that PCBs, dioxins and furans operate as promoters is based upon studies of laboratory animals only, is that true?

A The studies which tell us that PCBs, dioxins, and dibenzofurans are promoters of cancer were developed through laboratory animals and we have belief that they are relevant to humans. We **[69]** test them on animals. We believe that's relevant to humans.

Q Your opinion about PCBs, dioxins and furans being promoters is based upon studies of laboratory animals?

A Yes. And my reason for believing this is relevant to human studies is because all government agencies concerned with health believe that this is the case and that we can usually pre-detect, because humans also are in the animal kingdom. Human cells are nuclei, cytoplasm, mitochodria, endoplasmic reticulum and respond in similar fashion.

Q Object to the non-responsiveness to the answer after the word yes.

A I would object to your keeping — stating that laboratory animals are different from human animals. I believe that we are in the same kingdom. That's what I've been taught. That's what I

teach my medical students. We do teach them that what is in animals is related to human.

Q Object to the non-responsiveness. Now, is it your opinion that cigarette smoking was the initiator of Robert Joiner's lung cancer? [70]

A Well, that's an interesting question. We, of course, do not know whether the PCBs, dioxins and dibenzofurans also serve in an initiation function. One might — I would think that the cigarettes probably served as initiators and that the PCBs, dibenzofurans and dioxins probably more likely than not served as promoters of cancer. They may, in addition, also have served as initiators. These words aren't magical. They simply refer to whether the DNA is directly attacked or not.

* * * *

[71]

Q Based on your study in this area, what occurs when you administer the PCBs before the administration of the initiator in laboratory animal studies?

A As I mentioned previously, PCBs alone also cause cancer, and this has been shown in many studies. They do not need to be — to have a promoter given first. So that PCBs, dioxins and dibenzofurans have been described as complete carcinogens by Dr. James Huff of the National Institute of Health because when given alone they will cause cancer to laboratory animals and probably to humans.

Q Now, which chemicals are you speaking of there?

A I'm speaking of dioxin and dioxin analogs which would include dibenzofurans, PCBs and other structurally very similar chemicals.

* * * *

[72]

Q Did I understand you to say that this is all dose dependent?

A These chemicals cause cancer in a dose dependent fashion.

Q What is your understanding of the term dose dependent?

A That means in simple language, the more you give, the more toxic outcome you get.

Q Does it also mean that there is a threshold over which the chemical must reach in order to have any toxic effects?

A No. As Dr. George Lucier and . . . Angelika Tritscher, George Clark and others have shown, a threshold is not implied nor is it necessarily found on biochemical responses with these chemicals.

* * * *

[75]

Q Let's move to your second opinion which was that in your opinion, Robert Joiner had higher exposure than the average person to PCBs, dioxins and furans. On what facts do you base that opinion?

A The fact that he worked with these chemicals.

Q What other facts?

A The fact that he worked with these chemicals for many years, he handled PCB contaminated transformer oil, he breathed smoke, he was in an underground enclosed area with no [76] protective gear for years. The rest of us do not normally handle chemicals contaminated with PCBs, dioxins or dibenzofurans as part of our work. That's not part of the work of the major population.

Q What other facts do you base your opinion on?

A Those are essentially the facts that I base them on, as I do normally in the practice of occupational medicine.

Q Are there any other facts on which you can think of on which you base that opinion?

A The documents we've discussed, my interviews with the patient and his wife, documents provided me by Mr. Warshauer and his colleagues. . . . And I would perhaps even go a bit beyond that. I think it would be of less consideration than the others opinion which usually a physician would come to the conclusion, the ones I've just given you. But the fact that this patient had a four-tenths — 0.4 parts per million of total PCBs in his adipose tissue despite cancer chemotherapy, weight loss, weight gain after the exposure without protection and without customary protection against [77] toxic chemicals such as PCBs, dioxins and dibenzofurans, despite the fact that he still had 0.4 part per million of PCBs suggests to me that this is additional comf[i]rmatory evidence for exposure beyond that of the average. Which we know he had because of his job.

Q How many years did you assume Robert Joiner was exposed

to PCBs, dioxins and furans?

A I believe his exposure started on or about 1973, when I believe he started in the work, and continued at least until he began to wear protective gear and probably decreased in an amount — the protective gear was after that time in the mid-'80s.

* * * *

[78]

Q Looking at the affidavit of Robert Joiner, did you assume based on his affidavit that he would have had roughly ten years of exposure without the use of any protective equipment?

A Well, if he started in 1973 and somewhere after ten years began to wear protective equipment, I assume that he had exposure during those unprotected years.

Q Now, during those unprotected years, how do you quantify his level of exposure?

A There is no way of quantifying what has entered his lungs which is where he got the cancer and where it is the site of PCB metabolites. This is where PCB metabolites congregate and deposit. I assume that — it seems highly logical to me that he breathed PCBs, dibenzofurans and dioxins and so, there was an immediate passage through the lung [79] cells and to a certain extent deposition. We have no way of quantifying dose and target organ from that kind of exposure. There is no method that I know of published in the medical literature which would allow us to do that.

Q So, you have no opinion as to the level of PCB, dioxins or furans in Mr. Joiner's lungs?

A I have an opinion that it is above that which the general population would be exposed to.

Q But again, you cannot quantify that, can you?

A The exact amount, no, I cannot quantify the exact amount.

* * * *

[84]

Q What information do you have about the concentrations of PCBs, furans and dioxins in the mineral oil contained in the transformers that Robert Joiner worked around?

A We have specific data back that came by fax yesterday, and I showed you my entire file, showing that there were PCBs in some

of the mineral oil. And my general knowledge that dibenzofurans and dioxins are found in PCB-containing electrical transformer oils.

* * * *

[85]

Q What was the level of concentration?

A It varied from a few parts per million up to a few hundred parts per million in those that I looked at that came in yesterday.

Q Do you recall seeing any that were greater than a few hundred parts per million?

A I don't remember. I didn't look at every page.

Q Did you see any record that indicated any of these transformers contained pure Aroclor?

A No, I did not.

* * * *

[97]

Q Is direct tissue measurement of PCB, furan and dioxin levels in the human body from a fat biopsy preferable than a clinical history? It's better to have the fat biopsy than it is to take a clinical history from a patient for determining the measurement of PCBs, furans and dioxin in the human body?

A Well, for determining whether there is an exposure, it seems to me you are asking one question and applying the second. Maybe I'm wrong. If I am, please correct me.

If you are asking me how do I determine the amount of dioxins, dibenzofurans or PCBs in longer liver or adipose tissue. The only way in doing that, of course, is to measure it.

If, on the other hand, you are asking me as a physician can I come to a conclusion about whether a person has a higher intake than average or normal or that he or she would have otherwise by other means, and would I more usually use other means, then I would say sure. Usually physicians use other means. As you well know, Svenson & Rappee [98] in the Journal of Medicine. The fish were contaminated and when they measured the people's blood, the people's blood was also contaminated. The levels were higher in the fish. They were higher in the people. Did they do a $2,000 test on the person? Of course not. If the people ate the fish, of course, they had a higher intake. No insurance company in America would probably pay for a dioxin blood test. They would

think I as a physician would take a leave of my senses in ordering such an unusual test that's not considered anything other than a research technique at this time and is unnecessary to establish the clinical impression.

* * * *

[107]

Q As far as your methodology in reaching your opinion today, have you made an effort for determining the half-lives for specific congeners that were found in Robert Joiner?

A Of PCBs?

Q And furans and dioxins.

A I believe I summarized for you a few minutes ago what we know about dioxins and dibenzofurans half-life of secretion in healthy **[108]** adult human beings in our previous conversation. Do you want me to repeat that?

Q The question I asked you was: In your methodology in reaching the opinions that you have expressed today, did you make an effort to go back from scientific literature and determine the half-lives for the congeners that were found in Robert Joiner? Either you did or you didn't.

A What I don't understand is several things. My methodology for doing what?

Q Reaching your opinion.

A On what? Which opinion? We went over a number of opinions.

Q We have three opinions that you expressed. That he had a higher exposure than the average person. That there was some causal link, and you talked about when he had told you that he may have been aware that there was some contamination in some of the transformers. Now, those were your three opinions. My question is on your opinion about higher exposure, in your opinion about the causal linking that you reached in your opinion, in the scientific methodology that you used in reaching those two opinions, did you look at the **[109]** scientific literature to determine the half-life of any of the congeners found in Robert Joiner's adipose tissue? Either you did or you didn't.

A In the past year, I reviewed the literature for half-lives of PCBs, dioxins and dibenzofurans as a peer reviewer for the US Government on the dioxin and the dibenzofuran and separately the

PCB toxicological profile. I reviewed those and have those as part of my general knowledge. For the dibenzofurans and dioxins, the information appears to be better. They were part of my general knowledge which participated in my coming to conclusions.

* * * *

[112]

Q Now, are you aware of any animal studies that have been done on mice that would suggest that PCBs are a potent anti-carcinogenic agent? **[113]**

A There are studies which would show — which found less tumors of a certain kind in animals exposed to PCBs or to dioxins than in controlled animals under the circumstances of the experiment.

Q In other words, instead of being a promoter, it was an inhibitor?

A That could be one interpretation. Another interpretation is that it's a statistical fluke. The sample size was inadequate — this is something that's been considered and studied in many laboratories.

* * * *

Q Isn't it true that in your personal library that you have a container where you have collected a number of Dr. Safe's articles? **[114]**

A I've tried to collect most articles written about dioxins, dibenzofurans or PCBs.

* * * *

Q Do you agree that laboratory studies have established that the paralysis of chlorobenzene at temperatures of at least 600 degrees centigrade will yield dioxins and furans? **[115]**

A Yes. And they've also established it at lower temperatures.

Q How much lower?

A Well, that's a subject of debate. Incinerators seem to be producing it as the temperature goes lower on the way out. But that's certainly been well-documented.

Q Do you agree that laboratory studies have studies that for

paralysis of PCBs again you have to have temperatures of at least 600 degrees centigrade to produce furans?

A No. Your statement is not correct.

Q What minimum temperature is necessary?

A I don't know the minimum temperature, but in 200 to 600 degrees, you get a yield of PCBs being empirically converted to a reasonable larger yield of dibenzofurans and a somewhat smaller of chlorinated dioxins and the chlorinated benzenes of which you spoke previously. Again, in the 200 to 600 degree centigrade temperature will produce a yield to greater or lesser extent of chlorinated dioxins and/or dibenzofurans.

Q Now, in your scientific methodology in reaching your opinion, have you looked at any **[116]** scientific articles to determine the minimum temperature necessary when heating PCBs to create furans or dioxins?

A Yeah. I've talked to the people who published the articles and done the research, Keith Keesolie who showed that municipal incinerators produced de novo dioxins and dibenzofurans which did not exist in the household garbage being burned.

* * * *

[123]

Q Are there any human epidemiological studies that in your opinion support the opinions that you have reached in this case that PCBs were a promoter of lung cancer?

A The human studies I don't think focus the — quite so much on promoter versus initiator as to was there cancer and was there death due to cancer. In support of that, it seems to be reasonable to cite the study which frequently is cited which was performed by Kuratsune and colleagues in Japan where he found an increase in liver and lung cancer of — and cancer of the respiratory tract in some of the rice oil poisoned patients which were exposed to PCBs and dioxins and dibenzofurans. And he pointed out that in one geographical region, the cancer mortality was higher than the second geographical region, although the exposure was to people who lived in both areas.

And one possible explanation for this is that these were promoting the cancer formation and that there were other chemicals which were more prevalent in the people who lived in the geographical area where there was more cancer seen. This was one

of the studies that's cited for PCB and **[124]** dibenzofuran human promotion.

Q Other than Kuratsune, are there any other human epidemiological studies on which you rely in support of your opinions in this case?

A Well, I mean, there are human studies for cancer. Are you saying that the mechanisms be promotion only?

Q I took promotion out of the question.

A I understand you to be asking me broadly.

Q Correct.

A Yeah. I would cite the early human studies that suggested that this class of chemicals causes cancer in humans, leaving out the capacitor manufacturing cancer studies entirely. I would go to Hardell and colleagues on the chloracne and phemoxyherbicide exposed Swedish workers with an increase in certain kinds of cancer. Then I would — where he made the assumption that most likely the dioxin contaminants were one of the major ideologic factors.

The next series of studies that comes to mind would be the Fingerhut study that we mentioned for dioxin exposed to American workers, done by NIOSH, US Government Agency and then the IARC study, **[125]** International Agency on Research and Cancer, which is part of the World Health Organization, with an excess in cancer mortality and dioxin-exposed workers from a number of countries.

The next study I would think of would be the Zober study from Germany. The next study I would think of would be Thiess, more or less the same finding. German workers increase in gastrointestinal cancer when matched to suitable control group, dioxin-exposed workers. And Manz study on European workers exposed to dioxin with an excess of cancer death as compared to controls. And last, the Seveso studies with excess cancer mortality from — done by Bertazzi and colleagues.

Q That was the capacitor study, wasn't it?

A Yeah.

Q I thought you were going to leave those out?

A I was for the moment not focusing on the capacitor study. There are a series of those, as well, suggesting that PCB exposed capacitor workers may have an excess mortality. I was thinking instead of the Bertazzi dioxin exposed. I'm making the assumption

that dioxins, dibenzofurans are [126] structurally very similar and they appear to work in the human body for the most part, in going to the same receptor and cytoplasm and complex, going into the nucleus and starting everything off in this toxic cascade that we have very well characterized in animals and are increasingly characterized in humans.

* * * *

[127]

Q Was Mr. Joiner's level of dioxin found by Triangle laboratory well below background levels?

A Triangle Laboratory had a major problem for doing this. I give no credence to their results. They are not a World Health Organization. They did not take part in this round robin tests. And in any good laboratory result in human tissue, you should at least have a recognizable level for each of the 16 usually reported dioxins or dibenzofurans, and usually they had nondetect[able]. Which to me indicated they had a great deal of trouble in laboratory methodology.

Q Let me object to the responsiveness of the answer and ask the question again.

Wasn't the level of dioxin found in Robert Joiner's adipose tissue sample by Triangle Laboratories lower than the general background level? Either it was or wasn't.

* * * *

[128]

A My answer is garbage in, garbage out. They obviously have major problems with that laboratory analysis and I was a physician who is very experienced in that field and can give it no credence whatsoever.

Q Was the number which was reported below background levels?

A If the lab obviously had a major methodologic problem, I wouldn't use that in coming to a conclusion.

As we mentioned earlier, we described the numbers that I think are average for the United States, but that means you get results, you have a good lab doing good results. And as you know, the label error for dioxin laboratories is subsequently generally about 25 to 40 percent plus or minus. But you should have a number.

You shouldn't have nondetect[able].

* * * *

[130]

Q Do you know of any animal studies on respiratory effect in laboratory animals after inhalation exposure to PCBs, dioxins or furans?

A There are very few, if any, laboratory tests that have been done on animals with respect to respiratory toxicology of dioxins, dibenzofurans and PCBs. And I do not remember the content of the section on respiratory toxicology and the toxicologic profiles which I reviewed in the last year. I don't recall that at this point, if there [131] were any. I know that they are extremely sparse, if any.

Q For respiratory effects in general?

A No, for intake of the chemicals through the body. You can have intake through the gastrointestinal tract or the skin or the lungs. And if the chemicals then go throughout the body to the lungs or other parts of the respiratory system, you can and will have in some cases toxic effect in the target organ even though the chemical has come into the body and then gone into the target organ through the blood, regardless of the routes of entry.

Q Do you know of any animal studies on cancer in laboratory animals after inhalation of exposure of PCBs?

A I don't recall any at this time.

Q Do you agree that controversy still exists concerning animal studies and the quantitative relation between dioxin exposure and their possible toxic effect on humans and that those have not been sufficiently established?

A Any scientist will always conclude that further research would be of value. That's the way [132] we make our living and the way we make the world more certain. On the other hand, after the recent results in Lucier's lab, I think we have moved massively forward in understanding the relation between the levels which cause illness in animals and classically studied animals and human tissue responsiveness. We're moving markedly forward on the quantitative side.

* * * *

[157]

Q For General Electric Company, Westinghouse Company and Monsanto Company, was it ever said to you that laboratory results such as the ones that were performed by Triangle Laboratories on Mr. John Samples (six), that Triangle was not good for doing such laboratory work?

A I don't recall anyone saying that. I base my opinion on the fact that Triangle Laboratories did not take part in nor get certified [158] by the World Health Organization in interlaboratory validation studies for human tissue in either of the two round robin studies that have been conducted nor to the — those are the only two that I know of. And plus the fact that those results are completely unbelievable and in the practicing medicine, when you get back a result which is obviously off the wall, bears no resemblance [to] what you expect to see from a living human being, then you reject it and say there is something wrong in the lab. That happens 10 or 20 percent of [the] time in medicine.

* * * *

[169]

Q Are you saying that he came into contact to these PCBs through ingestion, dermal contact or breathing of vapors?

A By ingestion, gastrointestinal tract?

Q Yes.

A It would seem to me that he ate food without necessarily cleaning his hands and the food almost certainly on some occasions was contaminated with an excess of PCBs and dioxins and dibenzofurans from his job. And number two, he breathed without protective gear. Heated and unheated transformer [170] oil which, in some cases was contaminated with PCBs, and if PCBs, almost certainly dibenzofurans and dioxins. And third, he did not protect his skin from that, so his hands and face and neck and shoes and feet almost certainly got some transformer oil.

Q You are saying all three?

A Yes.

Q How much, can you give us any idea of quantity? Is it 1 percent more than the general population or 100 percent more or how much?

A I don't think it 's scientifically possible to come up with a good estimate, and particularly with respect to the target organ that

we're most concerned with, how much got into the lung.

Q Now, you've also said that the Triangle Lab report which showed his body burden —

A Which did not show his body burden.

Q You said it was defective. How was that test ordered?

A I have no idea.

Q You said that as a scientific — when you see a test you don't think is reliable, you repeat it or you ignore it? [171]

A Well, as a physician. First of all, I happen to be one of the people, the physician scientist who develops this kind of testing in humans in America. And so, I have a fair amount of experience as to when this looks believable and when I tell a chemist, you guys have goofed.

* * * *

[176]

Q Doctor, I just have a few more questions I'd like to ask following up about your scientific methodology.

As part of your opinion, are you assuming that the heating of the transformer cores created furans or dioxins, are you assuming that?

A I'm assuming that where PCBs were present, and they were present in some of these cores, I believe there probably was a certain degree of formation of dibenzofurans and dibenzo — dioxins. I'm also assuming that in general, it's my understanding of what we know in the field that as PCB containing transformer fluids are used, that there is a certain chemical change of PCBs and an increase in dibenzofurans and to a lesser extent dioxins.

Q But did I understand you to say you don't know the temperature that's necessary, the minimum temperature that's necessary to create furans and dioxins from the heating of PCBs, you don't know that number, do you?

A I don't recall what the lowest published [177] number at this point is and as I told you, it's my understanding of the literature that it's still an active topic of scientific chemical-type research as to what the lowest level would be. I don't think it's so much in doubt that PCB containing transformer oils do usually contain dibenzofurans in normal. I think that's well established. I believe it's fairly well established that there is a gradual increase of the dibenzofurans in PCB containing transformer oil.

DEPOSITION OF ROBERT K. JOINER

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

Deposition of Robert K. Joiner, taken in the above styled case on the 9th of June, 1993, in the County Commission Room of the Thomas County Courthouse, North Jackson Street, Thomasville, Georgia; commencing at approximately 9:10 a.m., before Judy B. Scott, Certified Court Reporter B-1487, Georgia.

* * * *

[2]
Whereupon, ROBERT K. JOINER, having been produced and first duly sworn as a witness, testified as follows:

* * * *

[85]
Q When you were draining this oil, just give us an idea on these small transformers, the smallest you have, which you said was a 2.5 —
A Very few of those, though.
Q But you might have a lot of fives?
A We've got a lot of fives, tens.
Q How much oil would be in there?
[86]
A Depending on the age and the style it was made four to fifteen gallons.
Q Even in a five, four to fifteen?
A Well, not a five, no; four to ten, maybe.

Q And then on up to the larger transformers, what type of volume capacity are we talking about?
A You're looking at literally hundreds of gallons.

* * * *

[100]
Q Now, prior to 1985 or '87, whatever that year is, there was simply no attempt to distinguish between a mineral oil or a PCB contaminated oil? You just treated them all as one and the same —
A Right.
Q — insofar as your physical contact with it?
A Right; I — no protection.
Q When did you first learn that there might be some problem with PCB in these oils?
A During all this changeover to put — give us protection.
Q Before that time, you did not know that?
A (Nodded in the negative.)
Q The City never gave you any information about it?
A (Nodded in the negative.)
Q So, at the time that the protective gear was furnished, that's the first time you had any realization that there could be some problem with contact with PCB?
A No, I cannot be sure of [the] exact dates.
Q Did you know you were working on transformers that had oils in them that could be PCB contaminated?
A Prior to that?
Q Yes, sir.
A (Nodded in the negative.)

[101]
Q You didn't know anything about that?
A (Nodded in the negative.)

* * * *

[189]
Q Now, you said there were two fires in the '70s in substations involving voltage regulators. Do you remember that testimony?
A Yes.
Q And the oil that was in those two voltage regulators spilled out and was ignited?

A Correct.
Q Who extinguished the fire, those two fires?
A We did, with a fire extinguisher.
Q Did you wear any sort of protective gear?
A None.

[190]

Q And the fire department was not called?
A Yes.
Q Did they assist in extinguishing the fire?
A We used their extinguisher.
Q Was the fire department there at the time?
A Yes.
Q Did they offer to you any of their protective equipment?
A No.
Q How long did it take you to extinguish those two fires?
A Ten minutes or fifteen. The smoke bellowed for a good while, but —
Q Now, in the substation, what else would have burnt in addition to the fluid that was in the voltage regulator?
A What do you mean; other associated equipment?
Q Yes.
A It burned the paint off of one regulator beside it and smutted up a few items. but it mainly contained to one regulator.
Q Anything that you can recollect that was burnt, other than the regulator and the paint on the regulator?
A The regulator was — the paint was burnt completely off. It destroyed the control cabinet on the front; it was burnt completely up.

[191]

Q Do you know how much fluid was actually contained in those two regulators? I'm not sure how — how much fluid are we talking about?
A Probably between 80 to 90 gallons per regulator.

* * * *

[200]

Q Back in the mid '80s, were you ever given anything to read about PCB contamination or PCB's, by either the Water and Light Department or MEAG or the EPA?

A Not MEAG; it wouldn't have anything to do with it.
Q Or EPA?
A I don't know what year it was when we started getting information. I just don't know.
Q And was there a period of time where there started to be posted notices around your work area as well?
A When I got sick.
Q Before that, they never posted anything at the [201] Water and Light Department?
A (Nodded in the negative.)

* * * *

[202]

Q Now, did your — most of the time — well, did you ever have nay problem with your nose or your throat burning when there was smoke?
A Uh-huh (affirmative response), correct; yes.
Q Was that just some of the time, but most of the time you didn't have the problem?
A Some of the time depending on how much smoke was available from baking.

[236]

Q Did you ever receive any information from Monsanto advising you that there were contaminants in PCB's, including polychlorinated dibenzofurans —
A No.
Q — and then trichlorinated dibenzodioxins that could be hazardous to your health?
A No.

* * * *

Q And did you ever receive any information from G.E. or Westinghouse that their mineral oil transformers had PCB contamination in them?
A No.

DEPOSITION OF
DR. WILLIAM CHARLES BAILEY

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

The deposition of DR. WILLIAM CHARLES BAILEY, taken pursuant to Notice and agreement of counsel and pursuant to the Federal Rules of Civil Procedure and the Federal reading and signing of the deposition; before Robin B. Myers, Certified Court Reporter and Notary Public in and for the State of Georgia; commencing at 9:05 a.m., Friday, October 29, 1993 at 1600 The Candler Building, 127 Peachtree Street, Atlanta, Georgia

* * * *

[4]

Whereupon,

DR. WILLIAM CHARLES BAILEY
was called as a witness herein and, having been first duly sworn, was examined and deposed as follows:

[8]

Q. What else do you have in your file relating to this case which you did not bring with you?

A. Well, you know, I don't have a file as such, but I reviewed all the medical records. I've got a two-volume set of medical records for the patient. I reviewed — I did a literature search about a year ago and then updated that, reviewed all the abstracts and

selected — and articles that related to PCB and human disease and everything I could find in the literature, plus the — these other attorneys had sent me a few articles, most of — some of which were actually duplicates of things that I'd found in — in my review of the literature initially. And then I did that again just about a month or so ago just to see if there was anything I had missed. I've got a couple of other ones there, reviewed all those, and just kind of generally reviewed the literature once again in the whole area of — of lung cancer, small cell carcinoma, specifically, and smoking-related problems and those represent sort of the — some things that I thought were pertinent to the particular issues at hand.

[9]

Q. How about depositions?

A. Yeah, now, actually that's right. I had a deposition from Arnold Schecter and a deposition from the — the patient and a deposition from a toxicologist from the University of Kentucky, Robertson, I think.

Q. Anybody else?

A. And the patient . . . . I think those were the only three depositions that I reviewed.

Q. Did you review anybody's summaries of depositions or did you review the actual deposition?

A. I reviewed the actual deposition.

Q. Did you actually read them?

A. Uh-huh (affirmative), yes.

Q. With respect to the medical records, did you actually read them or have someone review them for you and —

A. I believe I actually read those. Now, they were organized by somebody in terms of just Xeroxed and put together in a — in a two-volume set.

[11]

Q. How much time have you devoted to this particular case?

A. I would guess probably about 20 hours, something like that. I haven't really counted them up, reviewing all the data, primarily.

* * * *

Q. Do you have any written notes of any kind that outline your opinions or thoughts on this case?

A. No, I haven't written anything out. I've just reviewed a lot of literature and come to some [12] conclusions, but the conclusions were fairly straightforward.

[25]

Q. I had asked you earlier whether you had done any — if any of your recent writings had had anything to do with PCB exposure. I couldn't find any of your past writings to deal with any — to have anything to do with PCB exposure; am I correct?

A. That's right. I have never written anything about PCB exposure.

Q. And I'm also correct you've done no hands-on research in the field?

A. That's right.

Q. And that would include dioxins and furans?

A. Uh-huh (affirmative).

Q. Try to answer yes or no.

A. Yes.

[37]

Q. Tell me which articles that you have reviewed that you think are the leading articles in this field of PCBs that relate to the subject about which you are going testify.

A. Well, you know, I just don't have the articles at hand to really remember the specific authors of the different ones. I just reviewed all of them sort of in toto.

DEPOSITION OF WILLIAM J. WADDELL, M.D.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

The deposition of WILLIAM J. WADDELL, M.D., taken pursuant to Notice and agreement for cross-examination, discovery and any other purpose allowed by law and pursuant to the Federal Rules of Civil Procedure and the Federal Rules of Evidence; all formalities waived, including the reading and signing of the deposition; before Joyce S. Oglesby, Certified Court Reporter and Notary Public in and for the State of Georgia; commencing at 10:10 a.m., Tuesday, October 19, 1993 at 4000 One Peachtree Center, 303 Peachtree Street, Atlanta, Georgia.

* * * *

[4]

(Witness sworn.)

Whereupon, WILLIAM J. WADDELL, M.D., was called as a witness herein and, having been first duly sworn, was examined and deposed as follows:

* * * *

[30]

Q. You used animals as the group within which to study human carcinogens; is that correct?

A. That's correct.

Q. Did you think that was a scientifically valid method of study of these human carcinogens?

A. Well, it's the only way we can study humans, the kind of studies that I was doing because it's [31] unethical to do to humans what I did to the mice.

Q. Were the mice sacrificed?
A. Yes.
Q. Were the mice injected with known carcinogens?
A. Yes.
Q. And did you do this in order to extrapolate information from the mice's reaction to these injections so that you could extrapolate that information to humans, or did you do this just to see what happens to mice like my kid does with a magnifying glass and crickets?
MR. FLINT: Your kid does what?
MR. FREEMAN: That is hereditary.
BY MR. WARSHAUER: (Resuming)
Q. Do you know what I'm talking about?
A. Yeah, I know what you're talking about.
Obviously, the — the species of ultimate interest is the human, and we do things in experimental animals to see if we can gather any kind of information with which we can extrapolate to humans.
Q. Is that accepted in the scientific community to follow that procedure?
A. The procedure is to get all the information we can. We cannot extrapolate directly from experimental animals to humans, and that's why we do several species [32] and different strains, and we do all kinds of — If there was an acceptable animal species which responded just as a human, that's what we would all be using. But since there is none, we have to do what we can to do — get the information possible.
Q. But does the information have value with respect to humans?
A. Sometimes it does, and sometimes it does not.
Q. Within the scientific community, would you agree that the purpose of studies on animals is to be able to get information which can or may be extrapolated in humans?
A. That's the purpose.
Q. And that methodology of using animals is, in fact, scientifically accepted in the community as a whole?
A. The method is accepted — is accepted and is appropriate and proper, but the information cannot be blindly extrapolated to humans. It must be extrapolated with great caution.
Q. But the method of extrapolation, the process and the

practice —
A. The process —
Q. — of extrapolation is part of the [33] generally-accepted scientific methodology used here in the United States and in the world?
A. Of course.

[77]
Q. Now, we talked a little bit about the studies of PCBs on various animals. Do you think it would be appropriate to study PCBs on humans, not people who've already been exposed, but give them a dose, follow them along?
A. What would be the purpose of the study?
Q. To see what happens, I guess. What was the [78] purpose of your taking phenobarbital?
A. Well, I had a — I had a specific purpose, experimental design in mind, and I guess I'd have to know what the specific experimental design — what's —
Q. To see whether they get lung cancer.
A. That's unethical to give anyone something to see if it produces a carcinoma. That's unethical; I don't care what it is.

[113]
Q. Have you been provided with a copy of Dr. Teitelbaum's deposition?
A. No, I haven't.
Q. Are you aware of his opinions?
A. Not really, not —

[116]
Q. Did you read Dr. Schecter's deposition?
A. I read the excerpts prepared by Teitelbaum's staff.
Q. What did you think of his thoughts?
A. Well, I — I completely disagreed with his interpretation of what happens when you lose body fat. I think he's just going in exactly the wrong direction, and I think all the scientific information will back me up on that.
Q. What about his other opinions, that PCBs are not good for humans and nor are furans or dioxins?
A. I think he's exaggerating the information we have available.

DEPOSITION OF DR. PHILIP COLE

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

The deposition of DR. PHILIP COLE, taken pursuant to Notice and agreement for cross-examination, discovery and any other purpose allowed by law and pursuant to the Federal Rules of Civil Procedure and the Federal Rules of Evidence; all formalities waived, excluding the reading and signing of the deposition; before Joyce S. Oglesby, Certified Court Reporter and Notary Public in and for the State of Georgia; commencing at 12:10 p.m., Thursday, October 21, 1993 at 4000 One Peachtree Center, 303 Peachtree Street, Atlanta, Georgia.

* * * *

[4]

(Witness sworn.)

Whereupon, DR. PHILIP COLE was called as a witness herein and, having been first duly sworn, was examined and deposed as follows:

* * * *

[8]

Q. With respect to the medical records, did you mark them, tab them or otherwise notate them in any fashion?

A. I did not.

Q. Did you make any notes regarding them?

A. Yes, I did.

Q. Did you bring those with you?

A. They would — The ones that I considered the most important would've been incorporated into a sheet that I have that

represents that information and some other information as well.

[11]

Q. I'm going to show you Plaintiffs' Exhibit No. 5 which you have another eight-and-a-half-by-eleven sheet that says, "PCBs and Cancer: A Summary of the Literature." What is that, sir?

A. This is a tabulation of some of the results from a series of studies that have been done on people who are exposed to PCBs in the course of their work.

Q. Who did that?

A. I did.

Q. Did you read all of those studies?

A. Yes, sir.

[15]

Q. Are there any other documents that you have reviewed specifically and prepared specifically for this particular case?

A. I have read some other documents, yes.

Q. Which are the ones that come to mind as being most significant to this case?

A. Most significant?

Q. That's right.

A. I read the deposition of Mr. Joiner.

Q. Do you have that in your file?

A. I have it in my file, but in my office. I did not bring it.

Q. So, in fact, Schecter, the medical records and Mr. Joiner's deposition?

A. Correct. That is correct.

[37]

Q. Have you ever read any of the materials concerning PCBs and furans and dioxins prepared by Arnold Schecter?

A. I — I haven't read anything of Dr. Schecter's, other than his deposition in this case.

[42]

Q. Would you agree that there are scientists who believe that animal studies can be used as indicators for human reaction to a particular carcinogen or to the potential carcinogen?

A. Indeed there are. I'm one of them myself.

[75]

Q. You mentioned that there's a list. Where would I go to find a list that you would recognize? I know you just work from memory, and you may have inadvertently included one that's not on the list or included one — failed to include one that is on the list. I accept that as a possibility. Where would I go to find a list that you would recognize?

A. First, let me tell you that I didn't mention one that would not be on the list.

Q. Okay.

A. But I certainly did fail to mention some that — that are on the list.

The list that I like best, which is not to say that I subscribe to it across the board, is the list of Class I carcinogens put forward by the International Agency for Research on Cancer.

Q. IARC?

A. Correct.

Q. Do you recognize that group as a group that [76] is — whose opinions on cancer should be given a certain amount of credibility?

A. Let me say that there is no such thing as that group. The IARC is, in the context of which we're speaking, a convening body. It is not a authoritative body in and of itself. So, if I change your — if I change your question to be, "Are the results of the workshop groups convened by the IARC generally to be accredited?" the answer's yes, generally.

[105]

Q. Are you a believer that secondhand smoke is in fact a significant cause of lung cancer?

A. If you don't mind, I don't like to call it secondhand smoke.

Q. ETS.

A. Some of it is firsthand. Some of it has not [106] been expired by someone else, but it's coming off the cigarette. ETS, oh, yes, indeed.

Q. And what studies do you rely on?

A. There are about six or eight studies on this question. I can't cite them for you, but I would mention to you that the august body of the EPA has come to the conclusion that ETS should be taken as a recognized human carcinogen for the lung.

DEPOSITION OF STEPHEN B. HAMILTON, JR.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

Deposition of Stephen B. Hamilton, Jr., taken on behalf of the plaintiff in the hereinbefore entitled action, pursuant to the Federal Rules of Civil Procedure, before Melanie G. Collard, RPR-CM, duly qualified Notary Public in and for the State of Connecticut, at the Trumbull Marriott, 180 Hawley Lane, Trumbull, Connecticut, commencing at 9:05 a.m. on Wednesday, July 28, 1993.

* * * *

[4]

STEPHEN B. HAMILTON, JR., 154 Driftwood Lane, Trumbull, Connecticut, 06611, having been duly sworn, was deposed and said:

MR. WARSHAUER: This will be the deposition of General Electric Corporation taken pursuant to notice. I understand corporate representative on a number of topics is going to be Stephen B. Hamilton Jr. This deposition is taken pursuant to that notice and by agreement. We can waive all formalities and reserve all objections except as to the form of the question responsive thereto until such time as the transcript is sought to be used. Is that agreeable?

MR. COCHRAN: Yes. He's designated specifically on the health effects of PCBs and PCB mixtures and on the history of

General Electric's knowledge about health effects and General Electric's research concerning PCBs.

MR. WARSHAUER: Okay. He'll reserve signature?

MR. COCHRAN: Yes, please.

* * * *

[13]

Q When did you first become involved in the PCB issue?

A In 1981.

Q And why is it that you became involved in the PCB issue at that time?

A I took a new position in the company in something called Corporate Environmental Issues Project, and I was given responsibilities related to PCBs.

Q Prior to 1981, you had had no activities in that [14] field?

A That's right.

Q Did you follow it at all?

A Only in a very peripheral way.

Q Such as you knew that they had stopped making askarel transformers, for example?

A I knew that, yes.

Q Had you kept up at all with any of the literature about health effects or environmental effects of PCBs or its contaminants which might be PCDDs or PCDFs?

A Not at that time.

Q Once you became involved in 1981, what were the steps that you took to familiarize yourself with the subject?

A I did a number of things. One was to work through the NEMA organization, to interview a number of consulting firms that could assess the literature and provide a report regarding their assessment of the literature related to PCB health effects.

[35]

Q Am I correct that you have far less experience in the PCDD issue because you do not believe that PCD — I meant PCDD, you have far less on the dioxin issue because you don't see that dioxins are a contaminant or potential result of a change to PCB mixtures

used in askarels?

A I think that dioxin is much less of an issue related to PCBs than PCBs are to dibenzofurans. I would not agree that it is impossible that askarels would lead to dibenzodioxins under certain conditions.

Q It's possible, it's just not much of an issue?

A It's possible, but it only occurs apparently in rather unusual circumstances.

[51]

Q Do you think that PCDFs pose health risks to humans?

A I believe that PCDFs pose potential health risks to humans, and that's primarily based on the Yusho — that's Japanese — and the Yucheng — that's Chinese — incidents, both of which involved contaminated rice oil consumption. I do not believe that PCBs as — I'm sorry — PCDFs as contained in PCBs in electrical applications pose any additional risks to humans.

[84]

Q All right. With respect to Plaintiff's Exhibit No. 1, do you recognize that document?

A Yes, I do.

Q What is it?

A It's a letter from me to a Dr. J. Donald Millar, who is the Director of NIOSH.

Q That is November of 1982?

A Yes.

Q Am I correct in summarizing that letter by saying you are complaining to him about his characterization of PCBs as probable carcinogens? What's the term he used exactly?

A Let's see. I'm complaining specifically about the statement in the Federal Register, and I quote, "In animals and humans, PCBs have been found to be carcinogenic," in addition to several other sloppy-type errors that surprised me and disturbed me.

[88]

Q Have you read any of Dr. Schecter's works on the subject of PCBs?

A I read some of his papers.

Q Do you have an opinion as to their scientific validity?

A I think the data is probably about as good as could be obtained. He's worked with a lot of analytical chemists that are well regarded.

Q Do you disagree with his analysis?

A I can't think of any specific cases where I do.

MR. WARSHAUER: I'm done.

DEPOSITION OF THOMAS O. ROUSE

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

EXAMINATION BEFORE TRIAL of the Defendant, GENERAL ELECTRIC COMPANY, taken by and through its representative, THOMAS O. ROUSE, held at the Desmond Americana, Albany-Shaker Road, Albany, New York on July 27, 1993, commencing at 9:10 a.m.; before Paula M. Marcucci, a Shorthand Reporter and Notary Public in and for the State of New York.

* * * *

[3]

MR. WARSHAUER: This is to be the deposition of Thomas O. Rouse taken pursuant to notice of agreement taken primarily pursuant to a 30(b)(6) notice of General Electric, and I understand that Mr. Rouse will be testifying on behalf of the General Electric on various topics in this case. The 30(b)(6) notice to General Electric, specifically those topics relating to contamination of mineral oil dielectric fluids with PCBs, and, in addition, the formation of PCDFs or PCDDs as a result of arcing in transformers. Is that the basic topic that he's going to be talking about?

MR. COCHRAN: Yes. You comfortable with that?

THE WITNESS: Yes.

* * * *

[28]

Q Is PCB, in any of its congeners, an appropriate additive to mineral oil?

A Not that I know of.

Q Does it belong in mineral oil, dielectric fluids?

A It is not intended to be in any. General Electric uses, as a matter of fact, in the ASTM and in your local internal GE specifications there is a maximum of two parts per million PCB allowed. So, in a sense, the specification says there shouldn't be any measurable amount of PCB in the mineral oil.

Q We had a confusing discussion yesterday in the lower [29] limits of detection.

A The lower limits. What I'm talking about here are for method D-4059, which is also an AA method.

Q What that means is if there was one part per million, it would — no, if there was three parts per million, it would show three parts per million by that testing?

A That's a somewhat simplified but correct view of it.

Q Simplified but correct is the best I can hope for.

A I'd probably describe it much the same myself.

MR. COCHRAN: You can put "PPM" for parts per million.

A Or, if you would like, micrograms per gram.

Q Does PCB in mineral oil serve any beneficial purpose?

A PCB in mineral oil?

Q Yes, sir.

A Not that I'm aware of.

* * * *

[33]

Q Do PCDDs have any place in mineral oil transformers?

A They should not. I am not aware of any finding that suggests PCDDs are formed by the chlorination of any of the hydrocarbons in transformer oil.

Q How about PCDFs?

A I am not aware of anything that should involve the chlorination of the hydrocarbons in mineral oil for PCDFs. On chemical grounds, I would think it even less likely.

Q With respect to PCDFs and PCDDs, do they serve any useful purpose when contained in a dielectric fluid?

A I'm not aware of any.

Q Do they incr[illegible] the risk of harm to human health?

A I cannot answer that. That's not my area of expertise.

* * * *

[37]

Q But was there a need for the test whether it's done in the field or otherwise because General Electric was becoming aware that around one in every four mineral oil transformers had some level of PCBs in [38] them?

A The initiative for this program, as I recall it, came from the EPRI.

Q Did EPRI have some understanding that around one in every four transformers had some level of PCBs in them?

A I do not know.

MR. COCHRAN: Object to the form.

Q Do you know what level, what percentage of mineral oil transformers could be expected to have some level of PCB contamination?

A It has been estimated, in approximately 1988 or '89, that there was some 35 odd mineral oil containing — 35,000,000 odd mineral oil containing transformers in service in the U.S. My recollection of that same study indicated that there was some 2,000,000 thought perhaps to contain measurable quantities of PCBs and some 200,000 of those to contain in excess of 500 parts per million PCBs.

Q Would it surprise you, on a given utility, when they were running their test of dielectric fluids that they were finding between a fifth and a quarter of all of the transformers had some measurable level PCBs in them?

[39]

MR. COCHRAN: Object to the form. The question assumes facts that are not and will not be in evidence in this case, but go ahead.

A I am [neither] surprised nor nonsurprised by that.

Q Well, the numbers that you just gave me, if my math is right, would be about one in every 16 transformers roughly. Does that sound like the percentage you gave me?

A Something like that. I believe your math is correct.

* * * *

[49]

MR. WARSHAUER: Appendix A which is dated "Estimate 1988 PCBs Equipment Inventory File Report".

BY MR. WARSHAUER:

Q So, instead of the rough estimate we talked about earlier, 1 in 16, it's closer to 1 in 10?

A That's their estimate, yes.

Q And you think that sounds like a fair estimate?

A I'm sure they knew what they were doing in 1988. As I indicated a minute ago, I suspect that as older transformers are replaced in service, the number of transformers that contain traces of PCBs has gone down since replacement. New transformers do not have PCBs in them. I would think the numbers are somewhat lower today.

Q And the last date of potential contamination would have been 1977 when the industry stopped making PCB askarel transformers?

A Yes, and the regulation controlling the manufacturer [50] went into effect in '78. I'm sure there was action before that by the manufacturer.

Q When you checked back 10 years earlier than 1988, just as you expected, a decrease would exist in 1990. Would you find a slightly higher percentage in 1988?

A That's correct, and that report that we were just entering into the discussion, discussed a similar study that was done back in about 1980. And you're right, that's exactly what they concluded.

* * * *

[61]

Q Let's talk about the first one, oil's contamination. You mentioned to me that you all were not finding PCB levels in oil that arrived to the factory, so is this oil contamination taking place during the manufacturing process?

A We have found PCBs in the oil in our plant lines. The analysis that we performed that indicated that took place starting in about 1968.

Q Do you believe that your first contamination of mineral oil was 1968 or that's the earliest test that [62] you have where you —

A That is the earliest test that we have to indicate that.

* * * *

[67] Transformers are filled and drained for various purposes. A transformer could be inadvertently filled with askarel and drained into an oil line; equally so, a transformer could be inadvertently drained with oil and drained into the Pyranol line. There is no intention to do this sort of thing because Pyranol is considered, I believe, more expensive than oil, so it's a relatively precious commodity. Oil defeats the nonflammability aspect, character, of Pyranol, and Pyranol defeats the economics of use of oil; oil means that you're adding a higher cost fluid to a lower cost fluid to no purpose. So, in all cases, these kinds of actions of mixing were unintentional.

Q They were mistakes?

A What?

Q Were they mistakes?

A I think you could characterize them as mistakes.

* * * *

[69]

Q From 1935 — was that about the first date that General Electric first started putting PCBs in their askarel transformer?

A The records indicate 1934, 1935.

Q From that date until 1960, would it be fair to say distribution transformers that might have been contaminated with Pyranol PCBs would have been [70] manufactured at the Pittsfield facility?

A Yes, that's correct. There was a manufacturing plant for distribution transformers in Oakland, California from, I'm not exactly sure when it began; I would think in the '50s, and it was closed about 1973 and it was intended for supply of transformers to the far western part of the United States.

Q But did it use PCBs?

A It used both.

DEPOSITION OF DR. JOHN F. BROWN, JR.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

(Title Omitted in Printing)

EXAMINATION BEFORE TRIAL of the DEFENDANT, GENERAL ELECTRIC COMPANY, through and expert witness, DR. JOHN BROWN, conducted pursuant to the Federal Rules of Civil Procedure, before Lillian M. Cunniff, a Shorthand Reporter and Notary Public in and for the State of New York, held at the Desmond Americana, Albany-Shaker Road, Albany, New York, on Monday, July 26, 1993, commencing at approximately 12:30 p.m.

* * * *

[6]
DR. JOHN F. BROWN, JR., called by the plaintiff, having first been duly sworn by the Notary Public, was examined and testified as follows:

* * * *

[7]
Q What is your present occupation?
A My present occupation is Manager of Health Research at the named organization, General Electric Corporate Research and Development.

* * * *

[11]
Q By the mid 1980's, were you aware of any particular risk to human health associated with PCDD's or PCDF's?
A We had been following — I had been following the literature on alleged human health hazards since 1975

* * * *

[48]
Q Would you agree with me that it is foreseeable that in such instances PCDF's will exist at some level in PCB products, such as Aroclors?

* * * *

A I think I already testified that PCDF's can be found in electrical grade PCB's, at levels of from zero to two parts per million in what we have seen, and that these levels are toxicologically insignificant.

* * * *

[57]
Q It's your opinion that the dioxin group is a promoter, not an initiator?
A Yes. And again, it can serve as either a promoter or an inhibitor, depending on the animal test system.
Q Do you have an opinion as to its effectiveness as a promoter? Does it do a good job, or does it hardly promote at all?
A Dioxin is a material which has its pharmacological effect at very low levels; that is, it's a very potent agent either as a promoter or as an inhibitor.

* * * *

[61]
Q But you would agree PCDF's and PCDD's don't belong in either Pyranol or Aroclor?
A I think they were not intentional constituents, but they have always been there.

[97]

Q Are you familiar with the work of Arnold Schecter on the subject of PCB's?

A Arnold Schecter has written a hundred papers on PCB's and dioxins, mostly dioxins. I have not read them all.

Q Do you consider him to be authoritative; his papers?

A Just the papers?

Q The ones you have read, did you find them to be consistent with scientific knowledge and authoritative with something published in your line? [98]

A Where he has reported data on observed environmental levels, the results are as good as the laboratories doing the work. I have known Arnold Schecter for quite awhile. I'm rather skeptical of his interpretations, as are many other people, and I would not regard his interpretations of the analytical data he has gathered as scientifically authoritative.

EXHIBIT 3 TO SUMMARY JUDGMENT OPPOSITION

WESTINGHOUSE ELECTRIC
AND MANUFACTURING COMPANY
SHARON WORKS

Process Specification
No. SH-290504-A

April 12, 1945

PREPARATION OF TRANSFORMERS
AND COMPARTMENTS FOR SHIPMENT

GENERAL:

This specification covers the precautionary measures to be taken during the assembly and testing of transformers and compartments, to have assurance that the internal parts are free of contaminating material previous to shipment. Compartments may or may not be attached to transformers.

NOTE: This specification is a revision of Proc. Spec. No. 290504-A, dated March 18, 1938, issued at East Pittsburgh and is now being issued as a Sharon specification with the sub letter A.

CAUTION: DO NOT BREATHE VAPORS FROM INERTEEN. AVOID CONTACT OF IT WITH THE SKIN. WORKMEN SHOULD NOT ENTER A TANK WHICH HAS CONTAINED INERTEEN UNLESS THEY ARE WEARING PROPER RESPIRATORS, OR UNLESS THE TANK IS PROPERLY VENTILATED

* * * *

EXHIBIT 4 TO SUMMARY JUDGMENT OPPOSITION

Headquarters Medical Dept.
September 15, 1947

CLEVELAND WORKS
Mr. J.W. Wigert
Materials & Process Engr.

I am sorry for the long delay in getting the Safe Practice Data Sheet I-1 prepared. We are still lacking some data on inerteen, but rather than waiting until we get complete information I will send you the following, which takes care of most of the data. I discussed your capacitor installation with several persons at your plant sometime ago, including Mr. T.E. Fuller and Mr. J. Scott. They are familiar with the fact that inerteen is a fairly toxic material which must be handled in such a way as to prevent poisoning.

CONTAINERS AND STORAGE

I believe the type of container is indicated on P.D. Spec. 6935. You can probably determine the exact type of contained in which you receive this material from your supplier. There are no special precautions that need be taken in storing the original containers. In case of spillage, the inerteen should be cleaned up promptly so that its vapors will not contaminate the storage area. The use of oil absorbing compound, M#8695-1, is recommended since this compound absorbs the inerteen and keeps the floor in a non-slippery condition.

PROPERTIES

Fire — Non-flammable

Explosion — Non-explosive

BREATHING

I do not yet have data on the odor level of this material. Chronic poisoning may occur where there are repeated exposures or recurring exposures to a sufficient concentration of inerteen (6935) vapor over a period of months or years. Such exposures may produce internal bodily injury which may be disabling or could be fatal. Where people may breath air containing the vapor, the Maximum Allowable Concentration is one milligram per cubic meter. This Maximum Allowable Concentration applies to repeated or recurring daily exposures. If the concentration is less than one milligram, there is little chance of poisoning even after years of exposure. When much higher concentrations of vapor are breathed for a relatively short period, there may be irritations of the nose and throat, or, occasionally nausea. If air is saturated with inerteen vapor at room temperature, it will contain a concentration of .176 milligrams of inerteen per cubic meter of air. (Note) I am not entirely satisfied with this figure, although it is the best data that I have available. I expect to check this value before issuing the Safe Practice Data Sheet. Even though this relatively high concentration of vapor could be theoretically produced at room temperature, it must be remembered that its evaporation rate at room temperature is very slow and it would require long periods of time, in a totally enclosed space, to reach this saturated condition.

SWALLOWING

Inerteen is highly toxic if taken internally. The swallowing of approximately one or two ounces may cause serious internal injury or perhaps death.

SKIN IRRITATION

It is a mild skin irritant. Even though it is not very irritating to the skin, it is absorbed through the skin and can produce toxic reactions internally. It may also produce, after exposures of months or years, a skin condition known as chlor-acne. This condition is very difficult to heal.

PERSONAL PROTECTIVE EQUIPMENT

If it is necessary, under emergency conditions, to enter a space containing very high concentrations of vapor or fume, either a universal gas mask, M#6759-1, an air-line respirator, or a hose mask with or without blower, may be used. For usual concentrations of vapor, standard chemical cartridge respirator 8883-1, equipped with an activated charcoal cartridge 8883-2, will provide protection. These respirators should be of a type approved by the U.S. Bureau of Mines. Neoprene aprons and gloves 7530-6 may be used where necessary to protect the skin. If for any reason the neoprene gloves do not stand up well on this application, a glove made from Polyvinyl alcohol resin (such as Resistoflex) could be used. Hand cream, such as West 88 (West Disinfectant Company, 42-16 West Street, Long Island City), or Fend C (Mine Safety Appliances Company, Pittsburgh, Pa.) may be of some value as protection for the skin where better methods of protection are not practical.

PRECAUTIONS

Care must be taken to prevent any appreciable contact of this material with the skin, especially when these contacts are repeated. If any appreciable area of the skin becomes coated with the inerteen, it should be removed by washing with soap and water. Butyl stearate is a good solvent for this material and can be used to aid in completely removing the inerteen from the skin. Its use should always be followed by washing with soap and water. The Maximum Allowable Concentration of vapor, previously specified, should not be exceeded under normal working conditions. This can be accomplished either by using a totally enclosed system or by providing adequate ventilation. Where this is not practical, respirators may be used. Proper preplacement and periodic physical examinations should be made by the Medical Department on workers who work with inerteen.

FIRST AID

In cases of swallowing, vomiting should be induced immediately by carefully inserting a finger in the person's throat. In case of any severe exposure, the person should be placed under the supervision of the plant physician.

E.C. Barnes
Industrial Hygiene Engineer

ECB:y

EXHIBIT 8 TO SUMMARY JUDGMENT OPPOSITION

THE EPPLEY INSTITUTE
for
RESEARCH IN CANCER

November 19, 1975

Frederick R. Johannsen, Ph.D.
Toxicologist
Monsanto Company
800 N. Lindberg Blvd.
St. Louis, Missouri 63166

Dear Dr. Johannsen:

With regard to my letter of October 17, 1975 and our telephone conference concerning your data, I am happy to report that analyses are now complete. I would, however, first like to comment briefly on the methods of analysis employed and the possible conclusions.

When the data is analyzed from the life table approach, one concludes that mortality rates from all causes of death among this group of employees are not materially different from those which are expected on the basis of the national mortality experience. Indeed, this mortality is lower, on the average, than the national mortality.

The mortality due to lung cancer, however, ranges from between three- and ten-fold, when compared to the figure expected, and the increased rate is significant.

The third category of analysis was done from the perspective of the age at which employees were initially exposed. The deaths due to all causes show no discernible relationship between mortality and the age at which employees were exposed (see computer output tables). In the case of persons who died of lung cancer, the time intervals between initial exposure to the K Plant

and death are as follows: 9, 9, 17, 17, 19 and 26 years. Their ages at the time of hiring were 31, 33, 38, 42, 42 and 50 years and their ages when first exposed were 39, 43, 45, 45, 47 and 50 years (see the attached table). Furthermore, all six of the lung cancer victims worked for less than 3 years in the K Plant, and 3 of them worked for less than three and one half months. Therefore, it would be useful to look into their occupational backgrounds prior to their hiring by Monsanto. The absence of other information, especially with regard to their smoking habits, and the fact that the total number of employees in question (after considering those lost in terms of follow-up) is too small, make it difficult to attribute these lung cancer cases to the employment at K Plant.

It has been common practice in United States hospitals for the last 15 years to collect information on the extent and duration of the smoking habits of each lung cancer victim, and thus the smoking histories of the six cases under scrutiny should be obtainable from the corresponding hospital records. One may be able to judge the situation more clearly if this information were obtained and made available.

The results of this study do not indicate dose-response relationships, either for all causes of death or for lung cancer.

For your use, I will send all the computer output tables under separate cover. I will retain the information sheet you sent and the coding forms, unless you wish to have them returned.

Please do not hesitate to call me for additional consultation.

Sincerely,

/s/
E. Mahboubi, M.D.
Professor and Head Epidemiology

ah

* * * *

EXHIBIT 9 TO SUMMARY JUDGMENT OPPOSITION

Monsanto
From (Name & Location) Dept. Of [M]edicine & Environmental Health - F.R. Johannsen, A2SC

Date: August 27, 1976
Subject: Epidemiology
Reference: Krummerich Plant
To: G. Roush
A2SA

A group of 311 present/former W.G. Krummrich Plant employees have been compiled. Each of the 311 is known to have worked in Dept. 246, based on work history records. Information on the cause of death has been obtained on 50 former employees from this group. Evaluation of death certificates attribute 6 of those deaths to lung cancer.

A review of this population, omitting all those who worked in Dept. 246 for less than 6 months, yielded the following sub-population:

total number of employees	- 140
identified deaths (all cases)	- 23
deaths attributed to lung cancer	- 4

When compared to the 1969 U.S. male population, this group of 23 deaths would be expected to contain 1.24 cases attributable to lung cancer. Statistical comparison of the observed lung cancer versus the expected lung cancer yielded a highly significant chi X^2 value of 7.1. This number is even more significant than the value (chi $X^2 = 6.8$) obtained following evaluation of the full 50-person mortality population.

/ s /
Frederick R. Johannsen

alw

EXHIBIT 11 TO SUMMARY JUDGMENT OPPOSITION

Mortality of PCB Workers at
the Monsanto Plant in Sauget, Illinois

Judith A. Zack and David C. Musch

December 14, 1979

* * * *

[3]

The literature on PCB toxicity points to several organ sites in man that could potentially incur toxic effects of exposure to PCBs. The present study represents a completed analysis of the preliminary study of Monsanto PCB workers reported in 1976.

* * * *

[4]

Results

Eighty-eight of the eighty-nine members of the study cohort were traced. Fifty-eight were verified living and thirty were verified deceased by death certificate. The results of this vital status tracing are shown in Table 1.

The person-years of observation contributed by the eighty-nine member study cohort are shown in Table 2. A total of 1800.1 person-years were observed at all ages. Most of these person-years were observed in the middle-age range with 1333.1 person years (74%) observed for ages 35-60.

Table 3 categorizes duration of exposure to PCBs by vital status. For both living and deceased workers, the majority were exposed less than three years. The next frequent exposure class was for five or more years of exposure. The least number of workers fell in the three to five years of exposure category.

Overall, the average length of exposure for living and deceased workers was similar with deceased workers having 3.7 years of exposure and living workers having slightly less at 3.2 years.

The mortality experience for all males is summarized in Table 4. The mortality of white and nonwhite males is examined separately in Tables 5 and 6. Observed and expected deaths and SMR's are shown for each of the nineteen cause-of-death categories examined.

[5]

For all males, there were 30 deaths observe and 22.88 expected (Table 4). The overall SMR was 131. For malignant neoplasms, 8 deaths were observed with 4.46 expected. The SMR for all malignant neoplasm[s] was 179. No deaths were observed from liver or pancreatic cancer or from malignant melanoma. The SMR for lung cancer was high at 278. The only statistically significant difference seen in this table is seen for diseases of the circulatory system, exclusive of arteriosclerotic heart disease. Nine deaths were observed with 3.98 expected, yielding a SMR of 226.

Table 5 shows the overall SMR remains high for white males at 133. There were 4 deaths from cancer with 2.70 expected. None were from liver or pancreatic cancer or from malignant melanoma. The high SMR's seen in Table 4 for lung cancer and the residual diseases of the circulatory system appear to be explained by the high SMR's for these causes in white males. There were 3 deaths observed from lung cancer with 0.94 expected, yielding a SMR of 319. For the category of circulatory disease, exclusive of arteriosclerotic heart disease, the SMR was 526 with 7 observed and 1.83 expected deaths. This difference was the only one of statistical significance in this table.

For nonwhite males, there were no statistically significant differences seen in Table 6. The overall SMR was also high at 128. Four deaths from cancer were observed with 1.76 expected, but none from liver or pancreatic cancer or from malignant melanoma.

Case histories for the eight cancer deaths are summarized in Table 7.